A STUDY ON HOUSEHOLD CONTACTS OF SPUTUM POSITIVE PULMONARY TUBERCULOSIS PATIENTS IN COMMUNITY HEALTH AND DEVELOPMENT(CHAD) TUBERCULOSIS UNIT, VELLORE, TAMIL NADU

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CERTIFICATE

This is to certify that this dissertation entitled "**A STUDY ON HOUSEHOLD CONTACTS OF SPUTUM POSITIVE PULMONARY TUBERCULOSIS PATIENTS IN COMMUNITY HEALTH AND DEVELOPMENT (CHAD) TUBERULOSIS UNIT, VELLORE, TAMIL NADU**" is a bonafide work done by **Dr. LIAQUAT ROOPESH JOHNSON** in partial fulfilment of the rules and regulations for M.D. Branch XV (Community Medicine) examination of the Tamil Nadu Dr. M. G. R. Medical University, Chennai to be held in April, 2011.

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ABBREVIATIONS USED

ATT	Anti- Tuberculosis Treatment/ Therapy
CAT/ Cat	Category (of DOTS)
CHAD	Community Health And Development
CHC	Community Health Centre
CI	Confidence Interval
CMC	Christian Medical College, Vellore
DALYs	Disability Adjusted Life Years
DMC	Designated Microscopy Centre
DOT(S)	Directly Observed Treatment (Short-course)
DTC	District Tuberculosis Centre
DTO	District Tuberculosis Officer
GVMC	Government Vellore Medical College, Adukkamparai
HIV	Human Immunodeficiency Virus
IPT	Isoniazid Prophylaxis Treatment
ISTC	International Standards for TB Care
MO	Medical Officer
NGO	Non-Governmental Organization
NTP	National Tuberculosis Control Programme
PHC	Primary Health Centre
PHI	Peripheral Health Institution
RNTCP	Revised National Tuberculosis Programme
STLS	Senior TB Laboratory Supervisor
STS	Senior Treatment Supervisor
TB	Tuberculosis
TU	Tuberculosis Unit
WHO	World Health Organization

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INTRODUCTION

Tuberculosis (TB) has the dubious distinction of being the most persistent scourge of humankind. Worldwide statistics are staggering: in 2001, the WHO estimated that 1.86 billion persons were infected with tuberculosis. Each year, 8.74 million develop tuberculosis and nearly 2 million die. This means that someone somewhere contracts TB every four seconds and one of them dies every 10 seconds. The global community woke up to this disease when, in 1993, the WHO declared TB as a global emergency.[1]

In 2008, there were an estimated 9.4 million new cases, equivalent to 139 cases/ 100,000 population of TB globally. There were an estimated 11.1 million prevalent cases of TB in 2008 equivalent to 168 cases per 100,000 population. The South East Asia region accounts for 34% of the global TB burden.[2]

Though India is the second most populous country in the world, it has more new TB cases annually than any other country. In 2008, out of an estimated global annual incidence of 9.4 million TB cases, 1.98 million were estimated to have occurred in India, of whom 0.87 million were infectious cases, thus catering to a fifth of the global burden of TB. On a national scale, the high burden of TB in India is illustrated by the estimate that TB accounts for 17.6% of deaths from communicable disease and for 3.5% of all causes of mortality. The WHO estimated TB mortality in India was 276,000 (24/100,000 population) in 2008.[2] More than 80% of the burden of tuberculosis is due to premature death, as measured in terms of disability-adjusted life years (DALYs) lost. [3]

Every day, more than 5,000 people develop TB disease, and nearly 1,000 people die of TB, i.e. 2 deaths every 3 minutes. TB is also the leading killer of women, causing

more orphans than those produced by all causes of maternal mortality combined. Besides the disease burden, TB also causes an enormous socioeconomic burden to India. TB primarily affects people in their most productive years with important socio-economic consequences for the household when an individual falls sick with TB. The disease is even more common among the poorest and marginalized sections of the community. Almost 70% of TB patients are aged between the ages of 15 and 54 years. While two thirds of the cases are male, TB takes a disproportionately larger toll among young females, with more than 50% of female cases occurring before 34 years of age. In addition there is a devastating social cost – more than 300,000 children are forced to leave school because their parents have TB, and more than 100,000 women with TB are rejected by their families. The direct and indirect cost of TB to India for morbidity alone amounts to an estimated Rs. 12,000 crores ($3 billion) annually (in 2000). Studies suggest that on an average, 3 to 4 months of work time is lost as a result of TB, resulting in an average potential loss of 20-30% of the annual household income. This leads to increased debt burden, particularly for the poor and marginalized sections of the population. [4]

THE EVOLUTION OF TUBERCULOSIS CONTROL IN INDIA

1.1.1 NATIONAL TUBERCULOSIS CONTROL PROGRAMME (NTP)

The National Tuberculosis Control Programme (NTP) was launched in 1962. The strategy was based on early detection and treatment thereby converting infectious cases to non-infectious and preventing non-infectious cases from becoming infectious.

Diagnosis was made through radiology and sputum microscopy. Free domiciliary treatment (Short Course Chemotherapy) was provided through the Primary Health Care Services by establishing a District Tuberculosis Centre (DTC) in every district.

The programme suffered from poor managerial control, inadequate funding, over reliance on X-Rays, non-standard treatment regimens, low rates of treatment completion, and lack of systematic information on treatment outcomes.

Program reviews showed that only 30% of estimated tuberculosis patients were diagnosed and only 30% of those were treated successfully. [5]

1.1.2 REVISED NATIONAL TUBERCULOSIS CONTROL PROGRAMME (RNTCP)

On the recommendations of an expert committee, a revised strategy to control TB was pilot tested in 1993. The RNTCP applies the WHO recommended Directly Observed Treatment, Short-course strategy (DOTS). Full nationwide coverage

was achieved in March 2006, covering over a billion people (1164 million) in 632 districts/ reporting units.

1.1.2.1OBJECTIVES OF RNTCP

1. To achieve and maintain a cure rate of at least 85% among newly detected infectious (new sputum smear-positive) cases, and

2. To achieve and maintain detection of at least 70% of all such cases in the population.[6]

1. JUSTIFICATION

2.1 INTERNATIONAL STANDARDS FOR TUBERCULOSIS CARE

The purpose of the International Standards for Tuberculosis Care (ISTC) is to describe a widely accepted level of care that all practitioners, public and private, should seek to achieve in managing patients who have, or are suspected of having, tuberculosis. The Standards are intended to facilitate the effective engagement of all care providers in delivering high- quality care for patients of all ages, including those with sputum smear-positive, sputum smear –negative, and extra pulmonary tuberculosis, tuberculosis caused by drug resistant Mycobacterium tuberculosis complex (M. tuberculosis) organisms, and tuberculosis combined with Human Immunodeficiency Virus (HIV) infection.

The basic principles of care for persons with, or suspected of having, tuberculosis are the same worldwide: a diagnosis should be established promptly and accurately; standardized treatment regimes of proven efficacy should be used with appropriate treatment support and monitored; and the essential public health responsibilities must be carried out. Thus, all providers who undertake evaluation and treatment of patients with tuberculosis must recognize that, not only are they delivering care to an

individual, they are assuming an important public health function that entails a high level of responsibility to the community, as well as to the individual patient.

The Standards should be viewed as a living document that will be revised as technology, resources, and circumstances change. As written, the standards are presented within a context of what is generally considered to be feasible now or in the near future.

The Standards are also intended to serve as a companion to and support for the patients' Charter for Tuberculosis Care developed in tandem with the Standards. The Charter specifies patients' rights and responsibilities and will serve as a set of standards from the point of view of the patient defining what the patient should expect from the provider and what the provider should expect from the patient.

STANDARDS FOR PUBLIC HEALTH RESPONSIBILITIES

Standard 16 states that all providers of care for patients with tuberculosis should ensure that persons (especially children under 5 years of age and persons with HIV infection) who are in close contact with patients who have infectious tuberculosis are evaluated and managed in line with international recommendations. Children under 5 years of age and persons with HIV infection who have been in contact with an infectious case should be evaluated for both latent infection with M. tuberculosis and for active tuberculosis. [7]

Thus, contact screening is a standard of care issue, and not merely an additional responsibility of the care providers.

Tuberculosis is almost exclusively transmitted through air from patients with pulmonary disease. The risk of transmission is greatest if the index case is ‘‘sputum smear positive’’, and is directly proportional to the bacillary density in respiratory secretions. Therefore, proximity and persistence of contact are major determinants of the risk of transmission of infection, and those living within the same household are at higher risk than casual contacts. Among household contacts, those who are very young and those with absolute or relative immunodeficiency states are at increased risk of acquiring infection from the index case. Delay in the diagnosis and treatment of patients increases the risk of disease transmission to their contacts. [8]

Contacts of patients with infectious TB constitute a high-risk group for acquiring *M. tuberculosis* infection, as approximately 30% of close contacts demonstrate evidence of infection, and at least half of infected contacts exhibit progression to disease in the first 2 years. The risk of acquiring infection with *M. tuberculosis* among contacts may increase with increasing closeness of the contact and with increasing infectivity of the index case, resulting from environmental factors such as overcrowding and social factors including poverty. Investigations of close contacts of infectious TB patients constitute a key target in TB control because they can detect new recent infections with *M. tuberculosis* . Because newly infected contacts are at high risk for progression to active TB, contact investigations should be prioritized over other TB screening efforts to prevent substantial future TB cases. Household contacts of an infectious TB patient are a particularly high-risk population for latent infection with *M. tuberculosis* and for development of active TB. [9]

Household contacts form a high yield group for selective case finding by radiological and other methods of screening. It is always advisable following notification of a case of tuberculosis that appropriate contact procedures be initiated with the aim of identifying other cases of tuberculosis. If the first notified or index case is one of primary tuberculosis, contact tracing is done to locate the source case; and if the index case has smear positive post-primary or reactivation tuberculosis, the concern is that other contacts may have been infected by the index case, although a source case may still be sought. Contacts of a tuberculosis patient are 10 to 60 times more likely to have the disease than the general population according to some studies, and approximately 10-14% of all notified cases have been detected by contact screening.[10]

It is generally accepted that 30% to 50% of household contacts of adults with infectious forms of pulmonary TB will become infected. The risk for young children with untreated infection to develop TB is up to 43% in children <1 year of age and about 24% for children 1 to 5 years of age. [11]

The major risk for contacts lies in exposure to the infectious case before diagnosis.[12]

Whereas the first priority of tuberculosis (TB) prevention and control programs is identification and treatment of all persons with active TB, the second priority is contact investigation to find persons who were exposed to TB patients and to evaluate and treat them for latent TB infection (LTBI) and active TB disease.[13]

Contact investigations continue to be one of the highest yield methods of active case finding.[14]

Contact investigations are a major cornerstone of public health practice because they can detect new TB cases and prevent future cases. Because newly infected contacts are at substantial risk for progression to disease, contact investigations should be prioritized over other TB screening efforts. Coincident with this prioritization, efforts are needed to enhance the effectiveness of contact investigations. Of paramount importance is improving the elicitation of contact information from case patients. Techniques such as the social network approach, routinely used in sexually transmitted disease control, deserve evaluation. Once all contacts have been identified, selecting those who are at highest risk of becoming infected and progressing to disease requires systematic collection of salient information. The need for complete information collection to assess contact risk was underscored by Reichler et al, who found that there was documentation of the sputum smear results in only 38% of contact records and of the length of exposure to patients in only 1% of contact records. The final and necessary steps in contact investigations are completely evaluating contacts for disease and beginning therapy when infection or disease is identified. Case contacts have a high risk of developing active TB in the first 2 years following infection.[10]

The goal of tuberculosis control programmes is to eliminate the disease by breaking the chain of transmission, which can be effectively achieved by rapid identification and effective treatment of infectious cases. Once these cases are detected, it is

imperative to detect infected persons in contact with them so that the chain of transmission can be broken. Therefore, in recent years contact tracing has started gaining importance and is now incorporated into the Revised National Tuberculosis Control Programme of the Government of India.[8]

The revised strategy of National Tuberculosis Control Programme lays more emphasis on cure of infectious cases. The case finding activities are given lesser priority. It is stated that effort at increasing case finding should be made only after achieving 85% cure rate in already detected cases. The revised strategy is in line with the recommendations made by World Health Organization. This, however, does not mean that the contact examination (a case finding activity), which was being carried out as a routine practice in various tuberculosis centres should have been discontinued, because this activity was available in the centers which also provided ideal treatment facilities. Contact examination has a valuable impact on health education and impresses on the family and community as a whole, the infectious nature of the disease and the need for proper and regular treatment. This results ultimately in greater adherence to treatment and improved cure rates. Moreover, contacts form an easily approachable group and can be motivated easily.[15]

However, in a cross-sectional study conducted in four randomly selected TB units (TUs), two in an urban (Chennai City) and two in a rural (Vellore District) area of Tamil Nadu, South India, from July to September 2008, it was found that of 220 contacts aged <14 years, only 31 (14%) had been screened for TB, and that of 84 household children aged <6 years, only 16 (19%) had been initiated on Isoniazid

Prophylaxis Treatment. The treatment cards of source cases lacked documentation of contact details.[16]

Need for conducting a study among household contacts of sputum positive tuberculosis patients in a rural area in South India.

i) There is a scarcity of data regarding adherence to the guidelines regarding management of household contacts of sputum positive pulmonary tuberculosis patients under the RNTCP.

ii) Household contacts form a high risk group for acquiring Tuberculosis infection from a case of sputum positive pulmonary tuberculosis. Obtaining data regarding contacts may help appropriately reassign Programme priorities.

iii) Screening of symptomatic household contacts identified by the study may yield new cases, thus improving the case detection rate.

2. AIMS AND OBJECTIVES

3.1 To study the type of care received by the household contacts of sputum positive pulmonary tuberculosis patients in CHAD Tuberculosis Unit in relation to RNTCP guidelines.

3.2 To assess awareness among patients regarding screening of household contacts of sputum positive pulmonary Tuberculosis.

3. LITERATURE REVIEW

4.1 CONTACT SCREENING IN TUBERCULOSIS

The rationale for giving high priority to tracing and identification of contacts of newly identified tuberculosis patients lies in the relative ease with which such contacts may be identified and the expected high prevalence of recently acquired infection in this group.[17] There are four areas that must be addressed when considering contact investigations in countries with high tuberculosis case rates. The first concerns epidemiologic issues, the second the diagnosis of latent infection or tuberculosis, respectively, in contacts, the third the interventions to be chosen, and finally, how an efficient contact investigation scheme can be implemented in a national program.

It is a widely held conviction that active case finding among contacts of newly identified patients with potentially transmissible tuberculosis is an activity with a high yield. In industrialized countries it has been shown to be a cost-effective intervention. [18] In North America, 2–4% of close contacts are commonly found to have clinically manifest tuberculosis at the point of investigation,[18,13] and up to one third is found to be latently infected. Much higher prevalences have been reported when tuberculosis was more frequent in industrialized countries and from low-income countries. [12,19-24]

Although contacts of newly diagnosed tuberculosis cases can be found across all age groups, the identification of recently acquired infection is more easily distinguished from a long-standing infection in younger rather than older contacts. Thus, although

infection among contacts is discussed here for various age groups, the emphasis is on contacts who are children.

Table 1. Prevalence of tuberculous infection and tuberculosis among household contacts of tuberculosis cases in high incidence settings.

Study area and time	Index case characteristics	Contacts examined		Prevalence of infection n(%)	Prevalence of Tuberculosis n(%)
		Age group (years)	Number examined		
Norway-Oslo, 1940-53	76% smear positive	0-4	1012	490(48.4)	224(22.1)
		5-9	607	392(64.6)	167(27.5)
		10-14	499	366(73.3)	83(16.6)
Korea-Seoul, 1954	80% smear positive	0-4	454		62(13.4)
		5-9	470		31(6.6)
		10-19	865		91(10.5)
India-Madras, 1956-57□		0-4	101		25(24.8)□
		5-14	163		15(9.2)□
Kenya-Kiambu, 1959	Smear positive	0-5	82	24(29.3)	10(12.2)
		6-9	90	54(60.0)	14(15.6)
		10-14	77	52(67.5)	10(13.0)
India-Tumkur, 1960-61		0-4	69	8(11.6)	
		5-9	53	28(52.8)	
		10-14	64	40(62.5)	

□Incidence (attack rate) over 5 years of follow-up.

A study conducted in Kenya in 1959 showed that 30% of children aged less than 6 years who lived in the same household of a sputum smear-positive case had a tuberculin skin test reaction in excess of 8 mm induration. The prevalence of clinically active tuberculosis was several times larger in children who were household contacts compared to the general population.[24] These findings in Kenya confirm the findings from a survey conducted in Tumkur, India, at about the same time. [22] In the Indian survey, children aged under 5 years who were household contacts of bacteriologically confirmed cases had a prevalence of infection of 12% as compared to 2% in children in households without a case. [22]

While prevalence surveys among contacts provide an indication of the magnitude of transmission and the prevalence of secondary cases at the point of investigation, this underestimates the problem, as cases will continue to emerge over a prolonged period, as shown in a pre-chemotherapy study in the United States.[25] This emphasizes the need to include offering preventive therapy whenever such a screening program is carried out.

Most of these contact investigations have centered around patients with potentially the most infectious forms of tuberculosis and contacts living in close proximity with them. It must therefore be kept in mind that, judging from extensive and/or modern approaches to contact tracing, a considerable proportion of persons recently infected by the index case will never be found. [17,26]Nevertheless, the available data suggest that with some exceptions, investigation of close contacts, particularly children, is a high-yield activity. [27]

If children are targeted in a contact investigation scheme, adequately diagnosing active tuberculosis can be very difficult. [28] Various scoring methods have been proposed to diagnose tuberculosis in children. The method perhaps based on the most comprehensive data collection from various countries unfortunately includes tuberculin skin testing results, and is thus unlikely to be widely applicable.[29] The first problem is thus to determine the presence of tuberculosis in a child without tuberculin skin testing. In addition, even if tuberculin skin testing is available, an initially negative test would require continued follow-up examinations subsequent to identification of the index case. In this context it may be noted that in the Madras investigation, 8 per cent of the initially tuberculin negative contacts developed tuberculosis during the first year of follow-up. [21]

Role of contact examination and implementation of a sensible policy

High-incidence countries pursue a tuberculosis control strategy which has been defined as a strategy primarily targeted at reducing the incidence of tuberculous infection through identification of potential transmitters of tubercle bacilli in the community, i.e., largely sputum smear-positive cases.[30] Using sputum smear microscopy among symptomatic contacts of all ages, only 0.8% of cases were found among contacts of sputum smear-positive index cases in a study in eastern Nepal.[31] Contact investigations for such cases is thus not a particularly efficient activity: more than 100 people must be examined to identify a case in a population (contacts) which appears to be at about 10 times the risk of the general population, while only about five to 10 tuberculosis suspects spontaneously presenting with relevant symptoms need to be examined to identify a case. [32] On the other hand, a study in Malawi

identified contact tracing as a highly efficient activity for finding other than infectious cases, with a frequency of 7% of cases among contacts of newly identified sources of infection. [33]

A model has suggested that identifying and treating even a moderate proportion of recently infected persons will accelerate the elimination of tuberculosis much more efficiently than preventive therapy of persons with other than recently acquired infection. [34] While this generic model probably holds for both high and low-incidence countries, the staff in high-incidence countries is often overworked just by the task of controlling active, infectious tuberculosis. Importantly, it will not usually be possible to identify the majority of recently infected persons through simple case finding schemes among readily identified contacts.[17] Adding elements of an elimination strategy, i.e., identifying persons already infected, must thus be considered very carefully. Clearly, any group that is targeted should have an expectedly high prevalence of tuberculous infection, be at particularly high risk of progression to tuberculosis, and be readily accessible to examination.

The International Union Against Tuberculosis and Lung Disease (IUATLD) thus recommends limiting contact tracing to children under the age of 5 years who live in the same household as a sputum smear positive case.[35] Those found healthy should be given isoniazid and those found ill considered for treatment of active tuberculosis. Nothing other than a clinical examination is recommended. There are several reasons for this recommendation. First, it targets the most vulnerable group, most likely in contact for a prolonged period of time (more so than older children who may be more

frequently absent from home). Second, preventive therapy is unlikely to create resistance even if a healthy looking child actually has active tuberculosis, as children of that age as a rule have a small bacillary load. Finally, the index case can be requested to provide preventive therapy to the child. The duration of treatment might pragmatically be for the same period as the index case is being treated. In countries using 8-month regimens, this duration would be close to optimal.

Children in close contact with a sputum smear positive case are also logistically one of the most easily accessible groups, and one would think that both the index case and the health care provider would agree on the desirability of preventing such children from getting tuberculosis. Although the risk of tuberculosis is higher the more recent the infection, cases may continue to emerge long after the diagnosis in the index case. [36] Thus, reactivation of the infection when such children reach adolescence and adulthood might be successfully prevented through early preventive chemotherapy.

This is especially true, considering that in a recent study BCG scars were not significantly associated with transmission. Despite vaccination with BCG, a positive TST in a child who has had close contact with an infected adult is assumed to most likely represent infection with *M. tuberculosis*. Treatment of this latent infection should be considered, especially if the child is younger than 5 years. [37]

Studies have generally shown a grading in the indicators of transmission (active tuberculosis and LTBI) by closeness and duration of contact with the infectious

source. [38] However,a recent report found that current factors such as age, size of the household, sharing the same bed, number of people living in the same house and BCG scars were not significantly associated with the presence of a LTBI. [39]

There is evidence that contagiousness is not an all-or-nothing phenomenon and is affected by several factors, only one of which is the bacteriologic status of the patient's sputum. Although untreated smear negative, culture positive patients are less contagious on average, they still may transmit infection to their close and casual contacts. Compared with contacts with tuberculin conversion, persons who are already tuberculin positive have much lower risk of developing active tuberculosis after exposure, and persons with prior BCG vaccination are at somewhat lower risk.[40]

A study conducted in Brazil identified a significant number of people who, due to their proximity to the index case, run a great risk of being infected, as principally observed in the children of index cases (24.7% of which became infected). [41]

In a study carried out with infant contacts in the same household, it was clear that the parents were the most frequent source of infection for the children. Among the children who had contact with more than one source of infection, 35.3% developed the disease, and, when the source of infection was the mother or the father, 12.4% developed the disease. [42]

The contacts who were married or living with steady partners represented the second largest category in a study (17.5%), revealing a greater chance of contamination, whether they were spouses or partners of the index cases.

The risk of developing the disease for a person whose spouse suffers from tuberculosis is 2 to 40 times greater than that of the population in general, which allows the investigators to conclude that the proximity of the contact is one of the important aspects to be considered in the transmission of the bacillus.[43]

Various studies have shown the importance of a one- or two-year clinical and radiological follow-up evaluation of the contacts of patients with active tuberculosis, principally those living under unfavorable socioeconomic conditions. [36]

The clinical form of the index case that was predominant in a study was the pulmonary form (seen in 87.3% of the cases), which ratifies the data found in the literature showing that the predominant form is the pulmonary form. [44]

Investigators in China have assessed the dose-response relationship between treatment delay of smear-positive tuberculosis patients and intra- household transmission. This is significant because little is known about the quantitative dose–response relationship between delay in TB treatment and household transmission.[45] It has been reported that a smear-positive patient who is not treated can infect approximately 10 individuals per year for an average duration of infectiousness of 2 years.[46] Under this circumstance, it was thought important to clarify the relationship between delayed TB treatment and household transmission. The objective of the study was to document the effect of treatment delay on latent TB infection among the household contacts of TB patients. A household contact was defined as any person staying in the index case's house for more than 3 months before the date of accrual. ‘Total TB treatment delay’ was the main independent variable. For TB patients, this was defined as the interval from

reported onset of symptoms to commencement of treatment for TB. The median total treatment delay of TB index patients was 69 days (mean 89.9 d, SD 62.9 d). Only 15 patients (3.8%) received anti-TB treatment within 30 days of the onset of their illness, whereas the majority (96.2%) had a delay of over 60 days. Three patients (0.8%) delayed more than 1 year. For total TB treatment delay, compared with baseline contact in univariate analysis, the risk of TST positivity gradually increased with prolonged duration of TB treatment delay (crude OR 0.79, 2.31, 3.20 and 3.41 for delay ≤30, 30–60, 60–90 and >90 d, respectively). After adjustment for other variables in the final model, the effect of treatment delay decreased but remained significant [adjusted OR (AOR) 0.61, 1.86, 2.37 and 2.27, respectively]. There was an increased risk of TST positivity for contacts of TB patients with chest X-ray presenting cavitation (AOR 1.64; 95% CI 1.25–2.21) and for contacts sleeping in the same bedroom with the TB patient (AOR 2.29; 95% CI 1.67–2.94). The investigators reported that thirty days delay in TB treatment seems to be the turning point at which a significant increase in risk for TB infection occurs. The risk of infection increases to around 2.3 times as the duration of delay reaches 90 days. Beyond that point the infection rate seems to level off.[45]

TB has enormous public health and economic implications in high-burden countries. There is therefore an urgent need to provide targeted interventions, particularly for those most at risk. Screening of household contacts, which has been prioritized in industrialized countries, merits serious consideration as a means to interrupt transmission in high-burden settings.

In high-prevalence low- and middle-income countries, household contacts have high rates of TB (5%) and TB infection (50%). It has been reported that the prevalence of TB infection and progression to active TB among household contacts exposed to drug susceptible and MDR-TB cases is comparable. Contact investigations could therefore be a cost-effective method for early detection of secondary cases of drug resistant TB.[47]

4.1.1 CLASSIFICATION OF CONTACTS

In a study conducted in the Tuberculosis Research Centre, Madras (now Chennai), contacts were classified into different categories using an elaborate process of assessment. Before an index case was accepted for treatment every effort was made to interview and examine in the Centre, by radiography and by tuberculin testing, all the family members (by blood or marriage) living in the patient's household. In addition, family members living elsewhere were sometimes interviewed and examined, either because they had attended with the patient or because they had come at the request of the medical staff to assist in the assessment of the co-operation to be expected from the patient and the immediate family. Although a number of contacts who were unrelated to the index case also attended and were examined, the present report is confined to a study of the family contacts. At the first and at each subsequent visit of a contact a record was made of the then current proximity of the contact to the index case, according to the following classification based on the family's cooking and accommodation arrangements:

4.1.1.1 GRADING OF CONTACTS

Cooking and feeding with the Index case	{5 Living in the same room
	{4 Living in a different room in the same house
	(3 Living in a different room in the same house
Cooking and feeding separately from the Index case	(2 Living in a different dwelling in the same courtyard
	(1 Living in a different house in the same neighbourhood
	(0 Living in a different neighbourhood

In addition, the duration of contact during the previous five years, and the period over which it had occurred, were recorded. The data so obtained were checked on several occasions during the first year of the follow-up, and before undertaking the present analysis they were systematically verified. All the family contacts were then classified as:

(1) " **close contacts** "-namely, those living, cooking and feeding in the same house as the index case (degree of contact 5 or 4) for the period of three months immediately preceding the start of treatment for the index case (including infants less than three months old); or

(2) "**remote contacts** "-namely, all those 5 or 4 degree family contacts who had not been in this degree of contact throughout the three months immediately prior to the start of treatment for the index case, and all the 3, 2, 1 or 0 degree family contacts.[12]

More recently, investigators have sought to classify contacts differently. Typically, contacts have been described as being either close contacts or other types of contacts.

Close contacts could be household contacts, nonhousehold relatives (relatives not living in the household) , leisure contacts, coworkers, or other types of close contacts.

Interestingly, in a study one-third of TB patients only identified household contacts.[13]

Others have described workplace and casual contacts. [64]

4.2 GUIDELINES ON SCREENING AND MANAGEMENT OF CONTACTS

4.2.1 CONTACTS

The WHO recommends that TB contacts should be clearly defined in terms of the type of contact, and the closeness and duration of exposure to the index case. All children in the household, especially those aged under 5 years, should be assessed for TB. High priority should also be given to contacts who have HIV infection and those with other underlying risk factors for TB. [48]

The RNTCP ,too, categorizes contacts as adult contacts and child contacts, specifying different courses of action for each type of contact.

The RNTCP clearly lists one of the roles ofMedical Officers as emphasizing on all sputum positive cases the importance of screening their contacts, and ensure that the symptomatic contacts are evaluated. [49]

4.2.2 PROCESS OF CONTACT INVESTIGATION

All identified prioritized contacts of the index case should be instructed to come to the health facility for evaluation. The evaluation may be limited to determining whether the contact has symptoms that may suggest TB. As a minimum, all adolescent and child contacts should be asked whether they have a persisting cough (>2weeks). Sputum smear examination should be carried out on those with a persistent cough. [48]

Close contacts of multidrug-resistant (MDR) TB patients should receive careful clinical follow-up for at least 2 years. If active disease develops, prompt initiation of treatment with a regimen designed to treat MDR-TB is recommended. On the basis of the currently available evidence, the World Health Organization does not recommend second-line drugs for chemoprophylaxis in MDR-TB contacts. [50]

4.2.3 PROVISION OF TREATMENT

Important considerations to be taken into account when providing treatment.

i) Any contact identified as having active TB should be registered and treated in line with the NTP policy.

ii) Children aged under 5 years who are close contacts and who do not have evidence of TB should be systematically treated with isoniazid chemoprophylaxis: 5mg/kg daily for 6 months.

iii) Children aged 5 years and above who are in good health do not require chemoprophylaxis but should be followed up on a clinical basis. [48]

India's Revised National TB Control Programme (RNTCP) recommends screening of all household contacts of smear-positive PTB cases, especially those aged <6 years, for symptoms of TB. For asymptomatic children and those found not to be suffering from TB disease, daily isoniazid preventive treatment (IPT) at 5 mg/kg is recommended for 6 months. To ensure that proper preventive chemotherapy is given to children, the Medical Officer should ask (or have the health workers ask) all smear-

positive PTB patients if they have children aged <6 years and ensure that they are brought to a health unit for screening. On the reverse side of the RNTCP TB treatment card, the number of household contacts (children aged <6 years) and the number of contacts placed on IPT can be recorded. [16]

Table 2. How to proceed with preventive chemotherapy in children under 6 years of age who were in contact with a smear positive case. [51]

<table>
<tr><th>IF:</th><th>AND:</th><th colspan="2">THEN:</th></tr>
<tr><td>The child has symptoms of tuberculosis</td><td>An MO determines (preferably in consultation with a pediatrician) that the child has tuberculosis</td><td colspan="2">A full course of anti tuberculosis treatment (CATIII) should be given.</td></tr>
<tr><td rowspan="4"></td><td>A tuberculin test is not available</td><td colspan="2">The child should receive preventive chemotherapy for 6 months (isoniazid daily-5mg/kg body weight).</td></tr>
<tr><td rowspan="3">A tuberculin test is available</td><td colspan="2">The child should receive 3 months if INH preventive chemotherapy and a tuberculin test should then be done.</td></tr>
<tr><td>IF:</td><td>THEN:</td></tr>
<tr><td>The child’s induration to the tuberculin test is <6mm in diameter</td><td>Stop the preventive chemotherapy and give BCG vaccination (if not previously vaccinated).</td></tr>
<tr><td>The child’s induration to the tuberculin test is 6mm or more in diameter</td><td>Continue isoniazid preventive chemotherapy for another 3 months.</td></tr>
</table>

4.3 CONSIDERATIONS IN CONTACT SCREENING

Whereas the first priority of tuberculosis (TB) prevention and control programs is identification and treatment of all persons with active TB, the second priority is contact investigation to find persons who were exposed to TB patients and to evaluate and treat them for latent TB infection (LTBI) and active TB disease.[13]

Most previous studies pertaining to household contact infection have focused on risk factors that are more likely to increase the concentration of the infecting droplets suspended in the environment. Those identified factors consist of the severity of disease, smear and cavitation status in TB case, family size, intimacy of contact and ventilation of the exposure environment.[45]

Other studies focused on the nature of possible case–contact interactions, such as contact age, immunosuppression and poverty status. [9,13,39,52]

Past studies of contact investigation focused on TB transmission and identification of active TB disease among contacts, finding greater transmission of TB infection from patients having sputum smear positive(+) for acid-fast bacilli (AFB) [53] and prevalence of active TB in 1.3 to 1.5% of adult or household contacts. [54] A contact investigation study in Australia examined outcomes other than transmission, finding an average of 6.5 contacts screened per patient, a median interval between case report and contact screening of 1 month, 36% of contacts as TB infected, and 61% of those started on treatment for LTBI as having completed.[55] However, a study conducted in India provides different figures. In the study, considering the number of close family contacts in the 341 families, 12 (3.5%.) of the index cases had no close family

contacts and the great majority of the families-namely, 88.3 %/-had five or fewer contact members. There were two families with nine contacts, one with 10 and one with 14. The average number of contacts for all the families was 3.3. Thus, including the index case, the average family consisted of 4.3 members.[56]

In a recent study conducted in the USA, the investigators found a median of 4 (average 6) close contacts per patient, ranging from 2 to 6 among the sites. It was noted that a visit by the contact investigation worker to the patient's residence during the investigation resulted in identification of two additional close contacts, which were likely to be children younger than 6 yr of age.[13]

A Chinese study on screening of household contacts identified a total of 1386 newly diagnosed active TB cases. Their 5392 household contacts were screened. The overall prevalence of active pulmonary TB among household contacts was 3.76%, but significantly higher in the age groups of <15 years or > or =55 years than the other age groups (chi2 = 15.381, P < 0.01). The rate of active pulmonary TB in household contacts was significantly associated with the amount of bacteria discharged from index cases (r = 0.998, P < 0.01). Through contact tracing, every 100 index cases could contribute in finding 15 more new active TB cases among household contacts.[57]

In a study conducted in Morocco, more than 1 million household TB contacts were identified in approximately 200,000 investigations over a 11 year period. On average, 77% of identified contacts were screened every year; overall prevalence was 2.5%. The proportion of TB cases identified in household contacts of registered cases was

5.6%. This was significantly higher in children under 10 years and in patients registered and diagnosed with symptomatic primary complex.[47]

Another study reported that the prevalence of tuberculosis infection among the contacts was 44% (763/1733). Tuberculin conversion was observed in 7.8% of contacts, and 31 new cases of tuberculosis were detected (1.8%). The percentages of tuberculosis infection, tuberculin conversion and case detection were higher among persons exposed to sputum smear-positive patients and among those in close contact with the index case. Contact infection was more highly associated with the bacteriological status of the index case and degree of proximity of exposure when the analysis was restricted to contacts less than 15 years old. Case detection was 4% among close contacts living with a sputum smear-positive patient.

The authors concluded that investigation into tuberculosis contacts offered a high yield of detection of infected contact persons and new tuberculosis cases, even among contacts of culture-negative pulmonary tuberculosis patients and contacts of extrapulmonary tuberculosis patients.[58]

A study conducted in Pakistan recently reported that household contacts of patients suffering from active pulmonary tuberculosis have more chances of being infected with Mycobacterium tuberculosis as compared to the healthy non-contact, as shown by the higher levels of antituberculous antibodies & positivity of Mantoux test.[59]

Another study was conducted to evaluate the risk for household contacts of tuberculous patients as compared to non-contacts.the investigators found that there was no difference in the average age of the household contacts and non-contacts. The

complaints of pyrexia, night sweats and weight loss were more in house hold contacts as compared to non-contacts. The awareness about BCG vaccination was equal in both. There were 49 contacts with positive Mantoux test while negative Mantoux test was found in 71 contacts. There were only three Mantoux positive among eighty non-contacts. There was no significant difference in the presence of IgM among household contacts as compared to non-contacts. However both IgG and IgA were present in significantly higher number of household contacts compared to non-contacts.[9]

More recently, other aspects of contact screening have begun receiving attention. A study in the USA identified several TB program practices or characteristics correlated with successful outcomes of contact investigation. One, the greater number of close contacts identified for drug-resistant and cavitary TB patients suggests that contact investigation workers expend greater efforts to identify close contacts of these patients. By doing this, TB programs reduce the risk of there being undiagnosed drug-resistant patients and prevent future disease among contacts, as well as identify the many infected contacts to potentially highly infectious patients. Two, a visit by the contact investigation worker to the patient's residence results in the identification of two additional (especially child) close contacts. Three, recording the date of last exposure to the infectious patient facilitates provision of follow-up TSTs to contacts initially TST(−), which is necessary to identify all contacts likely to convert to TST(+). Four, sites that use PHNs are more likely than those using outreach workers to start TST(−/unknown) high-risk contacts, who are possibly infected but anergic, or TST converters before their follow-up TSTs on presumptive treatment for LTBI. Five, the use of DOT increases the likelihood of LTBI treatment completion.[13]

Most recently, the updated summary of the Stop TB Strategy mentions:

Component 2. Address TB/HIV, MDR-TB and the needs of poor and vulnerable populations

a. Scale up collaborative TB/HIV activities.
b. Scale up prevention and management of MDR-TB.
c. Address the needs of TB contacts, and of poor and vulnerable populations.[60]
d. Clearly, the revision reflects the increasing concern about TB contacts among policy makers at the global level.

4.4 AWARENESS OF CONTACT SCREENING

In a recent study conducted in Tamil Nadu, the investigators attempted to ascertain the prevalence and awareness of contact screening among patients and health care workers.

Awareness about RNTCP contact screening and IPT policies among source cases was studied by an interview conducted in the local language (Tamil) by trained field investigators using a semi-structured interview schedule. This contained questions on the duration of symptoms, awareness of risk of transmission to family contacts, number of close contacts—especially children aged <6 years, screening for TB among children aged 0–14 years by symptom elucidation and relevant investigations (chest

X-ray, sputum examination), initiation of chemoprophylaxis, and treatment adherence and completion.[16]

There is currently no provision for documentation of the details of contact screening, IPT administration and follow-up, and these details therefore could not be elicited from the TB treatment card of the source case. The patient interview was thus considered as the most reliable source of information.

The study findings revealed that the knowledge that TB is transmissible to other family members was significantly lower among rural than urban patients (25/118, 21% vs. 113/135, 84%, $P < 0.001$). Among the 220 contacts aged 0–14 years, only 31 (14%) had been screened for TB disease. None of the child contacts screened was diagnosed with active TB disease. Of the 55 patients who had children aged <6 years, only 15 (27%) stated that they had been informed about the provision of IPT for their children.[16]

Another study conducted in Laos found that the awareness of the infectiousness of TB was low (30%) in case-patients, adults and child contacts. This raises questions about the quality of the given counseling and health education during DOTS at the concerned hospitals. This low level of awareness might explain the persistence of risky behavior such as indiscriminate spitting and close contacts while coughing or sleeping. Both, low awareness and risky behavior, might have contributed to the high proportion of LTBI in contact children in the study.[61]

4.5 MANAGEMENT OF SCREENED CONTACTS

Experience in IUATLD collaborative programs shows that most national programs have written recommendations in their manuals to offer preventive therapy to children under the age of 5 years who are in close contact with a newly discovered sputum smear positive case. Yet, the policy is rarely implemented. Only rarely are children who are household contacts called upon and examined, and preventive therapy in this group is rarely utilized (IUATLD, unpublished data). This rather disappointing observation may reflect the uncertainty about the role and the impracticality of contact investigations in high burden settings. It also indicates that the role of preventive therapy for groups that are more difficult to identify, in whom the risk of tuberculosis is lower or the risk of monotherapy higher, must be relegated to a lower priority for contact investigations as long as the most readily identifiable group, with a high disease risk and low risk of adverse events from the interventions (i.e., small children who are contacts of newly identified cases),is not routinely evaluated and treated.27

In a study conducted in South India, among children aged <6 years, only 16 (19%) had been initiated on IPT, with no difference between rural and urban groups.[16]

4. METHODOLOGY

4.1 DEFINITION OF TERMS

HOUSEHOLD CONTACTS

Those living, cooking and feeding in the same house as the index case for the period of three months immediately preceding the start of treatment for the index case (including infants less than three months old).[12]

INDEX CASE

The first member of a family suffering from sputum positive pulmonary tuberculosis to be registered in a DOTS Center.

SPUTUM POSITIVE PULMONARY TUBERCULOSIS

Sputum smear examination shows the presence of Acid Fast Bacilli on Ziehl-Neelson staining in at least one sputum sample.

DISTRICT TUBERCULOSIS CENTRE (DTC)

The District Tuberculosis Centre (DTC) is the nodal point for TB control activities in the district and also functions as a specialised referral centre.

The District Tuberculosis Officer (DTO) has the overall responsibility to implement the programme at the district level and is assisted by a Medical Officer (MO) and other technical and administrative staff.

TUBERCULOSIS UNIT (TU)

This is the sub-district unit of TB control activities and is usually based in health institutions such as Community Health Centres (CHC), Taluk Hospitals or Block PHCs. The population covered is approximately 5 lakhs (2.5 lakhs in hilly, tribal and difficult areas). A Senior Treatment Supervisor (STS) and a Senior TB Laboratory Supervisor (STLS) are based at the TU.

DESIGNATED MICROSCOPY CENTRE (DMC)

Designated Microscopy Centres (DMC) are usually situated at tertiary and secondary level health care institutions and Block PHCs or other equivalent institutions including private and NGO facilities. Each usually caters to a population of 1 lakh (0.5 lakh in hilly, tribal and difficult areas).

PERIPHERAL HEALTH INSTITUTIONS (PHIs)

For the purpose of RNTCP, a PHI is a health facility which is manned by at least a medical officer (even if the post is currently vacant). At this level are the dispensaries, PHCs, CHCs, referral hospitals, major hospitals, specialty clinics/ hospitals (including other health facilities)/ TB hospitals/ Medical Colleges within the District. All health facilities in the private/ NGO sector participating in RNTCP are also considered as PHIs under the programme. Some of these PHIs will also be DMCs.[6]

5.2 SETTING

The study was conducted in the Community Health And Development (CHAD) Tuberculosis Unit (TU). This tuberculosis unit is the redesignated Kaniyambadi Tuberculosis Unit, and is located in the premises of the CHAD Hospital, Bagayam. CHAD Hospital is the base hospital for the Department of Community Medicine of the Christian Medical College, Vellore. The Hospital primarily caters to the people of Kaniyambadi Block, but also receives patients from other areas of Vellore and Tiruvannamalai Districts. The CHAD Tuberculosis Unit caters to a population of 615,013 people.This was the base population for the duration of the study.

The details of Designated Microscopy Centres and the attached PHIs within the TU are given in Table4.

Table 3. Details of Designated Microscopy Centres and PHIs in CHAD TU

No.	Designated Microscopy Centre	ATTACHED PHI(s)
1.	ALANGAYAM	Alangayam PHC Nimmiyampet PHC Kavanur PHC Pudur Nadu PHC
2.	CHAD	CHAD Hospital, Bagayam
3.	GVMCH	GVMCH, Adukkamparai
4.	KAMMAVANPET	Kammavanpet PHC
5.	KANIYAMBADI	Kaniyambadi PHC Kathalampet PHC
6.	ODUGATHUR	Anaicut PHC Odugathur PHC
7.	PALLIKONDA	Pallikonda PHC Poigai PHC
8.	SRI NARAYANI HOSPITAL	Sri Narayani Hospital, Thirumalaikodi
9.	USSOOR	Alamelurangapuram PHC Ussoor PHC

5.2 STUDY DESIGN

The study is a cross-sectional study assessing the type of care received by household contacts of sputum positive pulmonary tuberculosis patients registered with CHAD TU. As part of the study, the investigator came in contact with the patients only once- during the interview.

5.3 STUDY METHOD

Direct interview with the respondents.

5.4 STUDY INSTRUMENT

Questionnaire administered by the investigator.

5.5 INCLUSION AND EXCLUSION CRITERIA

INCLUSION CRITERIA:

i) All sputum positive pulmonary Tuberculosis patients, more than 18 years of age, and

ii) Registered with the CHAD TU between July 2008 and June 2010.

EXCLUSION CRITERIA:

All sputum positive pulmonary Tuberculosis patients, more than 18 years of age, and registered with the CHAD TU between July 2008 and June 2010, who were unwilling to participate in the study.

5.6 OUTCOME MEASURES

The following outcome measures were studied:

i) Number of patients advised contact screening.

ii) Number of instances where contact screening was done.

iii) Number of instances where child contacts were initiated on IPT.

iv) Number of patients aware of the need to screen household contacts.

v) Number of patients aware of methods to perform contact screening.

5.7 SAMPLE SIZE CALCULATION

Sample size calculation done using the formula: $4\ pq/\ d^2$

Where p= prevalence

And d= precision

Assuming a contact screening rate of 30%

Precision:10%

Sample size: 4 (0.3*0.7)/(0.1*0.1) =84

5.8 DATA COLLECTION AND ANALYSIS

The proposal for the study was prepared and submitted to the Institutional Research Board, Christian Medical College, Vellore. The board approved the study.(Approval letter in Appendix 1.)

The questionnaire for the study was prepared and pre-tested in a pilot survey. Modifications were made to the questionnaire based on the experience of the pilot survey.

The investigator obtained the list of all sputum positive patients registered with the CHAD TU between July 2008 and June 2010 from the TB Register maintained at the TU. The addresses were entered into a specially created database using Microsoft Excel 2007.

Next, the addresses were scrutinised for completeness. The TU covers a vast area, hence the addresses were sorted by geographical location. This included sorting by place of residence/village and Block.

A list of all addresses was prepared for each calendar year, sorted according to the place of residence/ village Block.

The addresses have been classified into the following groups on the basis of follow-up:

Table 4. Classification of addresses included in the study

Serial Number	Type of Address	Description
1.	Contacted	The investigator verified the accuracy of the address either directly, or through Health Aide/ Volunteers.
2.	Interviewed	The investigator interviewed the patient after obtaining written consent.
3.	Unable to contact	The investigator was unable to contact the patients at their given addresses, and was unable to obtain any further information regarding their whereabouts.
4.	Unavailable	The address was correct. However, the patient was not at home on at least 2 occasions. These patients could not be interviewed.
5.	Migrated	The address was correct, but the patient does not reside there anymore. If the present address was known, the patient was traced at the new address and included as “contacted”.
6.	Unwilling	The patients at these addresses did not give consent to participate in the study.
7.	Died	The address was correct, but the patient had died. The investigator confirmed the status of the patient with survivors of the patient’s family.

The investigator then proceeded to physically verify the addresses by systematically covering all the villages in a Block before moving on to the next one.

Extreme care was taken to maintain the confidentiality of the patient. The investigator divulged the purpose of the visit only to the patient, after confirming that the person in question had received treatment for tuberculosis. Direct references to the illness were avoided whenever others were in the vicinity of the patient. Patients were asked whether they had obtained treatment from the Peripheral Health Institution that was purported to have provided DOTS, following which they were asked whether they had received treatment for Tuberculosis. If they responded in the affirmative, the investigator enquired whether other family members were aware of the illness. In situations where the patients had not disclosed their disease status to other family members, the patients were given the option of being interviewed at a neutral location. Many patients residing near the CHAD Hospital preferred being interviewed at CHAD Hospital; others were interviewed at a discrete location of their choice. In all other situations where the family was aware of the disease status, the interview was conducted in the patient's home.

The investigator then proceeded to explain the details of the study to the patient. Printed information sheets (in Tamil) were given to the patient. Written consent was obtained only after the patient's doubts/ concerns were fully clarified. On some occasions the patient was either residing alone, or had not disclosed the disease status to others. In such situations the investigator was unable to obtain the signature of a witness.

The questionnaire was administered by the investigator, and responses entered on the spot.

The questions asked pertained to general patient details, details of treatment and screening, and awareness regarding contact screening. In addition, details of all contacts were obtained. All child contacts were examined for the presence of BCG scar, and details regarding Isoniazid Prophylaxis Treatment(IPT) were obtained.

Wherever there was a child contact, or any symptomatic adult contact, the investigator referred the individual for screening. The said individuals were advised to go to the nearest Microscopy Centre or CHAD Hospital, according to their preference.

In addition, the investigator encountered patients who had completed their stipulated course of ATT, but who had not tested sputum following treatment completion; those who had defaulted on treatment, and those who were symptomatic again after being cured. These patients were also referred for further management to CHAD.

Data entry was done using Microsoft Excel and SPSS version 15.

Analysis was done using SPSS version 15.0.

6. RESULTS

6.1 BASELINE CHARACTERISTICS

The year wise break-down of patients is given in Table 5.

Table 5. Distribution of patients by year and inclusion status.

YEAR	TOTAL SPUTUM POSITIVE PATIENTS	NUMBER OF ADDRESSES INCLUDED	NUMBER OF ADDRESSES NOT INCLUDED
2008	167	131(78.4%)	36(21.6%)
2009	236	187(79.2%)	49(20.8%)
2010	160	20(12.5%)	140(87.5%)
TOTAL	563	338(60.0%)	225(40.0%)

Inclusion was stopped on obtaining the required sample size.

All values in brackets are the respective numbers expressed as a percentage of the total patients in the corresponding year.

Table 6. Details of patients included in the study

YEAR	TOTAL PATIENTS INCLUDED	NUMBER OF ADDRESSES UNABLE TO CONTACT	ADDRESSES CONTACTED				
			NUMBER OF MIGRATED/ UNAVAILABLE	NUMBER OF DEAD	NUMBER OF UNWILLING	NUMBER INTERVIEWED	TOTAL ADDRESSES CONTACTED
2008	131	91(69.5%)	5(3.8%)	10(7.6%)	5(3.8%)	20(15.3%)	40(30.5%)

2009	187	95(50.8%)	7(3.7%)	27(14.4%)	5(2.7%)	53(28.3%)	92(49.2%)
2010	20	5(25.0%)	2(10.0%)	1(5.0%)	1(5.0%)	11(55.0%)	15(75.0%)
TOTAL	338	191(56.5%)	14(4.1%)	38(11.2%)	11(3.2%)	84(24.9%)	147(43.5%)

- All values in brackets are the respective numbers expressed as a percentage of the total patients in the corresponding year.

Figure 1. Flow chart of patients

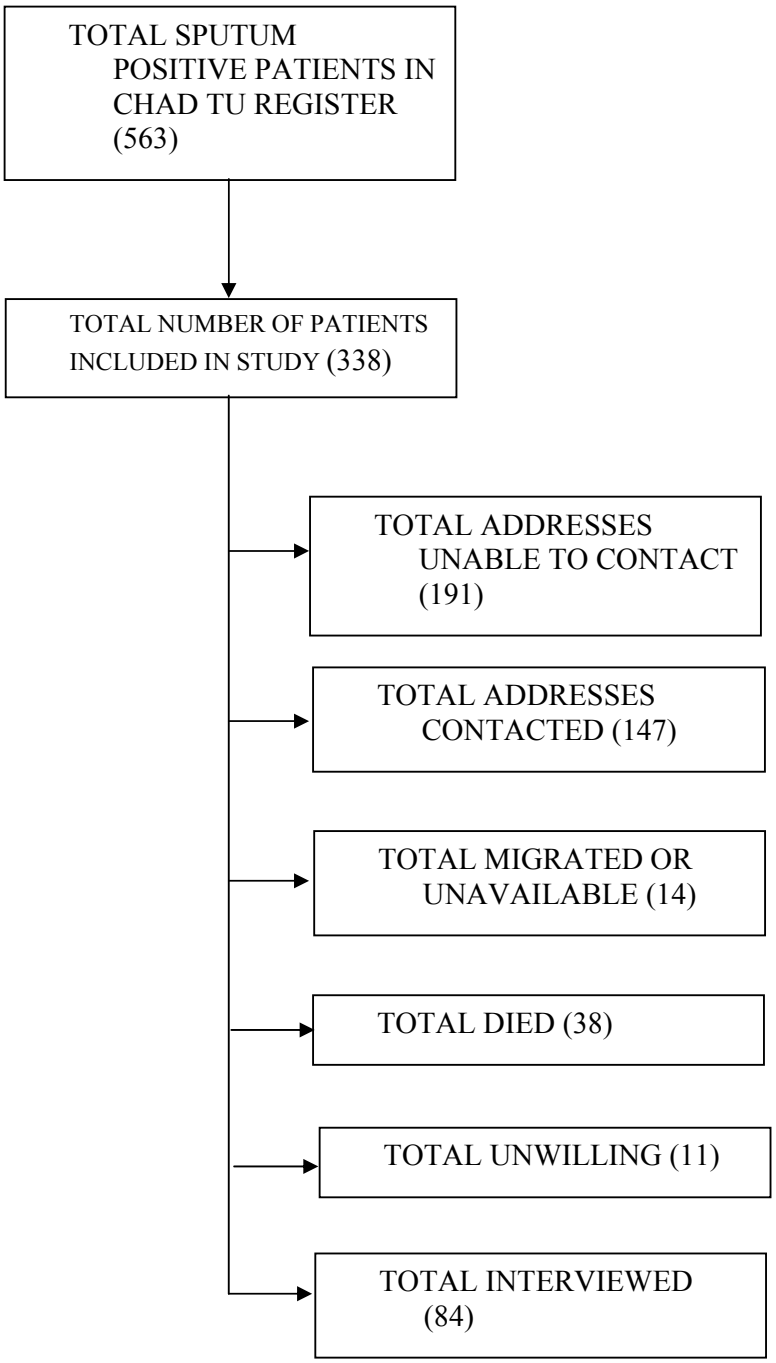


Table 7. Characteristics of Patients Interviewed (N=84)

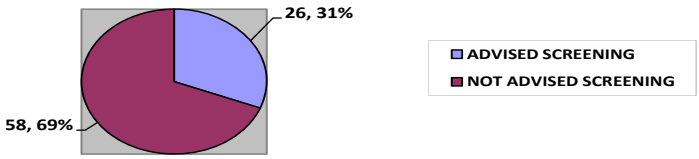
CHARACTERISTIC		**NUMBER (%)**
AGE	18-45	37(44.0%)
	46-60	29(34.5%)
	>60	18(21.4%)
SEX	MALE	61(72.6%)
	FEMALE	23(27.4%)
EDUCATION	NIL	15(17.9%)
	1-5	17(20.2%)
	6-10	40(47.6%)
	11-12	8(9.5%)
	ITI/DIPLOMA	3(3.6%)
	POST GRADUATE	1(1.2%)
OCCUPATION	UNEMPLOYED	35(41.7%)
	UNSKILLED LABOUR	12(14.3%)
	SKILLED LABOUR	24(28.6%)
	BUSINESS/ SELF EMPLOYED	6(7.1%)
	GOVT. SERVICE	6(7.1%)
	PROFESSIONAL	1(1.2%)
MARITAL STATUS	SINGLE	13(15.5%)
	MARRIED	57(67.9%)
	WIDOW/ WIDOWER	8(9.5%)
	DIVORCED/SEPARATED	6(7.1%)

Table 8. Characteristics of Patients Interviewed (N=84)

CHARACTERISTIC		**NUMBER (%)**
DOTS CATEGORY	CATEGORY I	54(64.3%)
	CATEGORY II	27(32.1%)
	CATEGORY IV (MDR-TB)	3(3.6%)
DISTANCE FROM PHI(KM)	UPTO 5	55(65.5%)
	6-10	20(23.8%)
	11-15	8(9.5%)
	16-20	0(0.0%)
	>20	1(1.2%)
FAMILY HISTORY OF TB	PRESENT	57(67.9%)
	ABSENT	27(32.1%)
TOTAL NUMBER OF CONTACTS (N=249)	MALE	179(71.9%)
	FEMALE	70(28.1%)

6.2 ADVISED TO UNDERTAKE CONTACT SCREENING

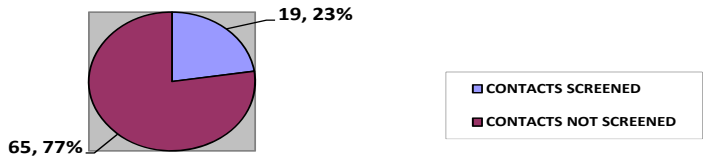
FIGURE 2. PATIENTS BY ADVISE TO SCREEN CONTACTS (N=84)



The above figure shows the details of patients by advise to screen contacts. As can be seen, only 26(31%) of the respondents were advised to screen their contacts.

6.3 SCREENED CONTACTS

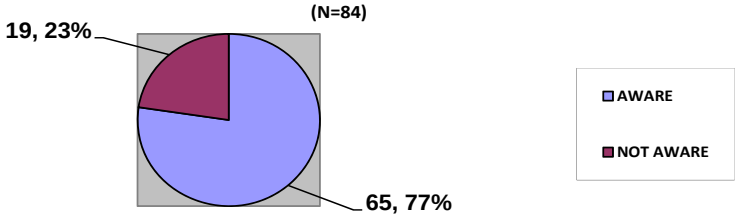
FIGURE 3. NUMBER OF PATIENTS BY CONTACT SCREENING (N=84)



The above figure shows details of patients by contact screening status. Only 19(23%) of the respondents undertook screening of their contacts.

6.4 AWARENESS THAT CONTACTS NEED TO BE SCREENED

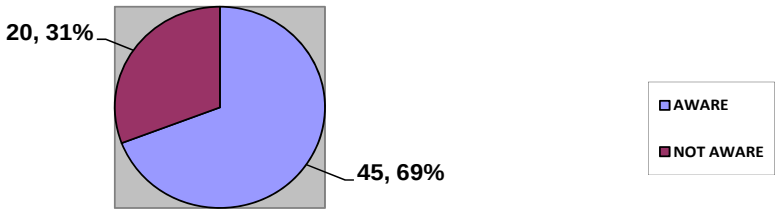
FIGURE 4. PATIENTS BY AWARENESS THAT CONTACTS NEED TO BE SCREENED (N=84)



The above figure shows details of patients by awareness that contacts need to be screened. Of the respondents, 65(77%) were aware of the need to screen contacts.

6.5 AWARENESS ON HOW TO SCREEN CONTACTS

FIGURE 5. PATIENTS BY AWARENESS ON HOW TO SCREEN CONTACTS(N=65)



The above figure shows details of patients by their awareness regarding how to screen contacts. 45(69%) of th respondents are aware of methods to screen contacts for tuberculosis.

Table 9. SUMMARY TABLE OF FACTORS CONTRIBUTING TO PATIENTS BEING ADVISED TO UNDERTAKE CONTACT SCREENING (N=84)

FACTOR	ODDS RATIO (95% C.I.)	p VALUE
MALE	1.023(0.497-2.106)	0.950
18-45 YEARS	0.932(0.487-1.781)	0.830
EDUCATED	0.489(0.264-0.907)	0.039
EMPLOYED	0.974(0.511-1.858)	0.936
MARRIED	1.066(0.532-2.137)	0.857
UPTO 5 KM FROM PHI	0.527(0.283-0.984)	0.046
SYMPTOMATIC OR CHILD CONTACTS PRESENT	2.743(1.528-4.924)	0.001
CHILD CONTACT PRESENT	2.509(1.395-4.510)	0.004
FAMILY HISTORY OF TB PRESENT	0.938(0.468-1.881)	0.857
ANY CAT II/ CAT IV	1.543(0.823-2.893)	0.181
ANY EVER TREATED DEFAULT/ FAILURE/ RELAPSE	1.333(0.682-2.607)	0.414
ANY DEFAULT	1.105(0.677-1.345)	0.785

Details of analysis cross-tabulations by various factors and outcome measures are present in Appendix 2.

Table 10. SUMMARY TABLE OF FACTORS CONTRIBUTING TO PATIENTS UNDERTAKING CONTACT SCREENING (N=84)

FACTOR	**ODDS RATIO (95% C.I).**	**p VALUE**
MALE	1.414(0.524-3.817)	0.482
18-45 YEARS	0.924(0.414-2.061)	0.846
EDUCATED	1.159(0.386-3.481)	0.789
EMPLOYED	0.519(0.233-1.157)	0.103
MARRIED	1.776(0.651-4.845)	0.239
FAMILY HISTORY OF TB PRESENT	1.535(0.699-3.374)	0.291
SYMPTOMATIC OR CHILD CONTACTS PRESENT	6.933(3.033-15.850)	<0.001
CHILD CONTACTS PRESENT	5.865(2.690-12.787)	<0.001
EVER TREATED RELAPSE/ DEFAULT/ FAILURE	2.700(1.272-5.733)	0.010
ANY DEFAULT	0.800(0.298-2.145)	0.651
UPTO 5KM FROM PHI	1.476(0.590-3.692)	0.392

Table 11.SUMMARY TABLE OF FACTORS POTENTIALLY INFLUENCING AWARENESS OF CONTACT SCREENING (N=84)

FACTOR	**ODDS RATIO (95% C.I.)**	**p VALUE**
MALE	1.155(0.858-1.555)	0.293
18-45 YEARS	1.310(1.045-1.641)	0.022
EDUCATED	2.138(1.142-4.003)	<0.001
EMPLOYED	1.396(1.060-1.839)	0.007
MARRIED	0.992(0.776-1.269)	0.952
FAMILY HISTORY OF TB PRESENT	1.319(1.080-1.612)	0.022
SYMPTOMATIC OR CHILD CONTACTS PRESENT	1.322(1.100-1.588)	0.031
CHILD CONTACTS PRESENT	1.310(1.090-1.575)	0.040
EVER TREATED FAILURE/ DEFAULT/ RELAPSE	1.063(0.828-1.363)	0.651
ANY DEFAULT	0.824(0.595-1.140)	0.175
ANY CAT II/ IV	1.054(0.834-1.331)	0.669
UPTO 5KM FROM PHI	0.963(0.760-1.220)	0.759

Table 12.SUMMARY TABLE OF FACTORS POTENTIALLY INFLUENCING AWARENESS OF HOW TO SCREEN CONTACTS (N=65)

FACTOR	ODDS RATIO (95% C.I.)	p VALUE
MALE	0.23(0.545-0.959)	0.068
18-45 YEARS	1.108(0.800-1.536)	0.535
EDUCATED	1.042(0.578-1.881)	0.886
EMPLOYED	1.023(0.723-1.447)	0.896
MARRIED	0.865(0.628-1.191)	0.401
UPTO 5KM FROM PHI	1.213(0.834-1.762)	0.280
SYMPTOMATIC OR CHILD CONTACTS PRESENT	0.984(0.686-1.410)	0.928
CHILD CONTACTS PRESENT	0.949(0.652-1.383)	0.782
FAMILY HISTORY OF TB PRESENT	1.169(0.852-1.605)	0.350
ANY CAT II/ IV	1.037(0.745-1.444)	0.830
EVER TREATED RELAPSE/ DEFAULT/ FAILURE	1.027(0.715-1.474)	0.888
ANY DEFAULT	0.788(0.485-1.278)	0.269

The factors found to have significant influence on the outcome measures were included in a logistic regression framework. Since there were no factors significantly influencing the awareness regarding how to screen contacts, that outcome measure

was excluded from logistic regression. Multiple logistic regression was performed for the following outcome measures: patients being advised to undertake contact screening; patients undertaking contact screening; patients' awareness regarding the need to screen contacts.

Table 13. Multiple Logistic Regression Analysis for a patient being advised to undertake contact screening

	B	**OR(95% CI)**	**Significance (p)**
EDUCATED	1.472	4.358(1.192-15.935)	0.026
RESIDENCE UPTO 5KM FROM PHI	0.995	2.706(0.924-7.925)	0.069
SYMPTOMATIC CONTACTS PRESENT	-1.890	0.151(0.047-0.489)	0.002

Table 14. Multiple Logistic Regression Analysis for a patient undertaking contact screening

	B	**OR(95% CI)**	**Significance (p)**
SYMPTOMATIC CONTACTS PRESENT	-2.817	0.060(0.017-0.216)	<0.001
EVER TREATED RELAPSE/ DEFAULT/ FAILURE	-1.225	0.294(0.077-1.123)	0.073

Table 15. Multiple Logistic Regression Analysis for a patient being aware of the need to undertake contact screening

	B	**OR(95% CI)**	**Significance (p)**
SYMPTOMATIC CONTACTS PRESENT	-2.358	0.095(0.009-0.983)	0.048
FAMILY HISTORY OF TB PRESENT	-0.534	0.586(0.098-3.510)	0.559
EMPLOYED	-1.335	0.263(0.075-0.928)	0.038
EDUCATED	-1.817	0.162(0.036-0.725)	0.017
18 TO 45 YEARS	-0.380	0.684(0.159-2.943)	0.610

6.6 MANAGEMENT OF CHILD CONTACTS

Table 16. Details of Child Contacts

TOTAL NUMBER OF CHILD CONTACTS	NUMBER OF CHILD CONTACTS NOT SCREENED	NUMBER OF CHILD CONTACTS SCREENED			
		RECEIVED IPT	DID NOT RECEIVE IPT	RECEIVED ATT	TOTAL
23	7(30.4%)	7(30.4%)	7(30.4%)	2(8.8%)	16(69.6%)

IPT= Isoniazid Prophylaxis Treatment

ATT=Anti Tuberculosis Treatment

Table 17. Details of referrals

CATEGORY	NUMBER REFERRED	NUMBER CAME TO CHAD
PATIENTS	25	10(40.0%)
CHILD CONTACTS	9	5(55.6%)
SYMPTOMATIC ADULT CONTACTS	6	3(50.0%)
TOTAL	40	18(45.0%)

Table 18. Details of contacts who came to CHAD Hospital (N=8)

CATEGORY	TOTAL NUMBER SEEN IN CHAD	SCREENING METHOD	TEST RESULT		OUTCOME
			NUMBER POSITIVE	NUMBER NEGATIVE	
CHILD CONTACTS	5	MANTOUX TEST	0(0%)	5(100%)	STARTED ON INH PROPHYLAXIS
SYMPTOMATIC ADULT CONTACTS	3	SPUTUM AFB X 2	2(66.7%)	1(33.3%)	SPUTUM POSITIVE PATIENTS STARTED ON CAT I DOTS

As Table 18. shows, of the 6 symptomatic adult contacts referred to CHAD, 3(50.0%) came for screening. Of these, 2(66.7%) were diagnosed to be sputum positive for Acid Fast Bacilli. The excess yield is 2.4%.

7. DISCUSSION

The characteristics of patients in this study (Table 7.) indicate that 61(72.6%) of all respondents were male. Other studies have reported the proportion of male respondents as ranging from 66.2% [45] to 75% [8,13,16,61]

The proportion of Category I patients was observed to be 54(64.3%). Investigators have reported 80% [16].

The mean age of respondents was found to be 46.6. This compares well with the reports of other investigators.[16,61]

The mean distance from the residence to the PHI providing treatment was found to be 5.29Km. This compares well with another study where the mean distance to the nearest health care facility was reported to be 4.7Km.[61]

The total number of contacts was 249, of which 61.8% were female. There were an average of 2.9 contacts per respondent. Elsewhere, investigators have found the average number of contacts to range from 3.3 [56], 3.6 [12], 6 [13]. However, the studies conducted in India are closer to the observed value. [12,56]

Overall, the findings on the baseline characteristics of respondents and their contacts seem to agree with those from other studies.

In this study, only 31% of all respondents had ever been advised to undertake contact screening (Figure 2.)

The results of the study (Figure 3.) indicate that the initial assumption that contact screening is being performed in only upto 30% instances (approx.) is true. The rate of contact screening in this study is 23%. In comparison, the prevalence of contact screening has been variously reported as 24-77%. [16,62] The value obtained correlates with that reported by Banu et al (study conducted in Tamil Nadu, with respondents from Chennai and Vellore).[16]

Among various reasons cited for the low rates of contact screening in India, low levels of awareness as well as poor motivation among health care workers to actually follow the guidelines stand out.[16]

In studies conducted in Africa, investigators reported distance, poverty and lack of facilities to conduct screening as major factors for lack of contact screening.

Interestingly, of all those who undertook contact screening, 8(42%) had not been advised to do so.

In this study, being advised to screen one's contacts is significantly associated with education and the presence of symptomatic or child contacts.(Table 13.)

Those who are educated are 4.35 times more likely to be advised to undertake screening of their contacts($p=0.026$).

However, the presence of a symptomatic or child contact during treatment protects against being advised to undergo contact screening (OR 0.151, 95% CI 0.047-0.489; p=0.002).

The implications of the above findings are two-fold:

i) The fact that literate patients are more likely to be advised to undertake contact screening is a double-edged sword. On the one hand, in regions where literacy rates are high, most patients will be advised to undertake contact screening. This will likely result in the detection of more patients. However, considering the reluctance of the health care workers to actually conduct the screening, it is unlikely to significantly impact the case detection rates. The burden of disease is likely to continue to remain unchanged, with a large number of patients undetected and untreated. On the other hand, in areas with low literacy rates, more individuals are likely to not be advised to undertake contact screening. These individuals are then likely to be detected at advanced stages of the disease, or after having received non-standard treatment. This will potentially increase the risk of mortality due to the disease, as well as the risk of developing a drug-resistant form of TB. Either situation doesn't bode well for the long-term success of the RNTCP.

ii) The significance of having a child or symptomatic contact resulting in the respondent not being advised to undertake contact screening lies in the fact that it is this high-risk group that actually needs to be advised and screened. However, in view of the low overall rate of screening, it seems reasonable to assume that many contacts are not

benefiting from this. The possible explanations for the finding that the presence of a symptomatic or child contact is likely to result in the patient not being advised to undertake contact screening are:

a) Not many (31% in this study) patients are being advised to undertake contact screening in the first place.

b) There is thus a higher chance that those with such contacts will be missed by the system under the present circumstances.

c) The patients themselves may not be disclosing the truth regarding their contacts even if they are asked about them. A study[62] revealed that patients were likely to bring their contacts to the health centre if there was a high intention to do so (Adjusted OR = 3.35, 95% Cl = 1.44-7.76). With many patients reluctant to disclose their disease status to even their closest family members, it is quite possible that patients deliberately withhold such information as might cause them to either disclose their disease status, or take other family members to the hospital for screening.

The factor that significantly influences the decision to actually undertake screening of the household contacts is the presence of a symptomatic or child contact (OR 0.060(0.017-0.216) (p=<0.001). However, as discussed above, the presence of a symptomatic or child contact is likely to cause the patient not to undertake screening. While this may appear counter-intuitive, the fact is that most patients prefer to receive

treatment under the cloak of non-disclosure. Doubtless, this is a reflection of the concern among the diseased that they may be discriminated against, should their disease status become public. Social stigma aside, the investigator discovered that many patients voluntarily isolated themselves within the house to prevent the risk of contagion (even where they had not disclosed their disease status to other family members). This only serves to underline the fear of the disease as well as public retribution.

Of the 23 child contacts, only 7(30.4%) received IPT. In addition, 2(8.8%) of the child contacts received ATT. These figures are higher than the 19% reported by another study conducted in Tamil Nadu.[16]

Among the respondents, awareness of the need to screen household contacts is 77%.

Similarly, the awareness that household contacts need to be screened is significantly influenced by the following factors:

i) The presence of a symptomatic or child contact (OR 0.095(0.009-0.983) (p=0.048).
ii) Being employed (OR 0.263(0.075-0.928) (p=0.038), and
iii) Being educated (OR 0.162(0.036-0.725) (p=0.017)

Those who are educated/ employed or have symptomatic or child contacts are less likely to be aware of the need to screen their contacts. Thus, while those who are educated are more likely to be advised to undertake contact screening, they are less likely to be

aware of the need to do so. It is possible that this is a reflection of the (extra) efforts most health care workers tend to take while explaining things to uneducated patients. Since they are considered to be unable to grasp concepts easily, they probably receive more attention from the system as a whole, either through more frequent health education interventions, or the mere process of simplifying concepts to the very basics to facilitate comprehension. Those who are educated on the other hand, are likely to be told just once, and that too using a lot of jargon. Consequently, it is the educated who are less aware. While this explanation is plausible, definite inferences cannot be deduced using the limited data collected as part of the study.

Of all those who were aware of the need to screen contacts, only 45(69%) knew how contact screening could be performed. Though this was not statistically significant, it has significant implications for the programme. Awareness is linked to attitude and behaviour.[61] Only when patients are aware of the details of the disease, how it is transmitted,etc., will they comprehend the risks of non-compliance with treatment as well as contact screening.

8. LIMITATIONS

The main limitation of the study was maintaining confidentiality about the illness while verifying addresses. The investigator had to struggle to explain the purpose of the visit to respondents, especially when other relatives and acquaintances (who were unaware that the patient had received treatment for TB) were also present. In those situations the investigator had to request a private audience with the patient, either in a nearby place, or at a location of the patient's choice.

Conversely, there were situations where the patient's illness was already a topic of discussion among the local people. These were patients who had been very irregular on treatment, or were very sick, or both. They had received numerous visits from other health care workers in the past, some of whom were (apparently) quite indiscreet. It was assumed that the investigator had visited the patient due to the illness, and on occasion, the same was enquired of the investigator to confirm their "suspicions". The investigator always gave deliberately vague responses to such queries so that the true purpose of the visit was not known. However, the success of this strategy could not be ascertained.

The other limitation was in terms of the ability of the respondents to comprehend the questions pertaining to the screening of contacts. This problem was acute in situations where the patient did not have any contacts. The response to the question, "Do household contacts need to be screened?" was invariably met with irritation that the question wasn't relevant to the respondent since (s)he did not have any contacts whatsoever.

The responses to the question, “How can household contacts be screened?” were also difficult to come by. The typical initial response was that it depended upon the Doctor. Responses were easier to come by when the respondents were well educated.

Since the required sample (N=84) was reached, the remaining patients were not contacted.

Lastly, the including the service providers in the study to ascertain their knowledge, attitudes and practices also would have provided the complete picture of the current situation. This could not be done due to resource constraints.

9. CONCLUSIONS

The major conclusions of this study are:

1. Among the respondents, only 31% were advised to screen their household contacts for the presence of TB.

2. Being advised to screen contacts is significantly associated with the education of the patient (p=0.026).The presence of a symptomatic or child contact (p=0.002) is likely to result in the patient not being advised to undertake screening.

3. Only 23% of all respondents undertook screening of their household contacts for TB.

4. Screening of contacts is significantly associated with the presence of a symptomatic or child contact (p=<0.001). Those with a symptomatic or child contact are less likely to undertake the screening of contacts.

5. Of the 23 child contacts, only 7(30.4%) were initiated on Isoniazid Prophylaxis Treatment (IPT). Two (8.8%) others were started on ATT following screening.

6. 77% of the respondents were aware of the need to screen their household contacts.

7. Awareness regarding the need to screen contacts is significantly associated with the presence of a symptomatic or child contact (p=0.048); being educated (p=0.017); and being employed (p=0.038). The presence of these factors is likely to result in the patient not being aware of the need to screen contacts.

8. Of all those who said that household contacts need to be screened, only 69% knew how this could be done.

10. RECOMMENDATIONS

Larger studies are needed to confirm the findings of this study.

It is also recommended that studies assessing the knowledge, attitude and practice of health care workers regarding management of contacts of TB patients be carried out.

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APPENDIX 1

APPROVAL LETTER FROM INSTITUTIONAL REVIEW BOARD TO CONDUCT THE STUDY

CHRISTIAN MEDICAL COLLEGE
VELLORE - 632 002, INDIA.
INSTITUTIONAL REVIEW BOARD (IRB)

February 22, 2010

Dr.Liaquat Roopesh Johnson
PG Registrar
Department of Community Medicine
Christian Medical College
Vellore 632 004

Sub: FLUID Research grant project NEW PROPOSAL:
A Study on the Household contacts of Sputum positive Tuberculosis patients with regard to following the guidelines of RNTCP in the Kaniyambadi TB Unit area
Dr. Liaquat Roopesh Johnson, PG Registrar, Community Medicine, Dr. K.R John, Dr. Reginald George Alex, Community Medicine.

Ref: IRB Min. No. 7097 dated 17.02.2010

Dear Dr. Johnson,

The Institutional Review Board (Ethics Committee) of the Christian Medical College, Vellore, reviewed and discussed your project entitled "A Study on the Household contacts of Sputum positive Tuberculosis patients with regard to following the guidelines of RNTCP in the Kaniyambadi TB Unit area" on February 17, 2010.

The Committees reviewed the following documents:

1. Format for application to IRB submission
2. Informed Consent Form and Information Sheet (English and Tamil)
3. Questionnaire
4. Cvs of Drs. Liaquat Roopesh Johnson and KR John.
5. A CD contaning document 1 – 4

The following Ethics Committee members were present at the meeting held on February 17, 2010 at 10:00 am in the CREST/SACN Conference Room, Christian Medical College, Bagayam, Vellore 632002.

Name	Qualification	Designation	Other Affiliations
Dr. George Thomas	MBBS, D.Ortho	Chairperson (IRB) & Orthopaedic Surgeon, St. Isabel Hospital, Chennai & Editor, Indian Journal of Medical Ethics	Non-CMC Staff.
Dr. Shuba Kumar	MA, MSc, Ph.D.	Dy. Chairperson (IRB) & Social Scientist, SAMRATH, Chennai.	Non-CMC Staff.

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CHRISTIAN MEDICAL COLLEGE
VELLORE - 632 002, INDIA.
INSTITUTIONAL REVIEW BOARD (IRB)

Dr. George Thomas, D.Orth
Editor Indian Journal of Medical Ethics
Chairman, Ethics Committee

Dr. Shuba Kumar, PhD
Deputy Chairman, Ethics Committee

Dr. L. Jeyaseelan, MSc,PhD
Secretary, IRB

Dr. George Mathew, MS,MD,FCAMS
Chairman, Research Committee &
Principal

Dr. Gagandeep Kang, MD,PhD,FRCPath
Deputy Chairman, IRB &
Additional Vice Principal (Research)

Dr. L. Jeyaseelan	MSc, PhD, FRSS	Professor & Head, Dept. of Biostatistics & Secretary IRB (EC), CMC	
Dr. George Mathew	MBBS, MS, MD	Principal, C.M.C.	
Dr. Thambu David (on behalf of Dr. Lionel Gnanaraj)	MBBS, MS, M.Ch. (Urol)	Medical Superintendent, CMC.	
Dr. Prathap Tharyan	MD, MRCPsych.	Associate Director, Professor of Psychiatry, CMC	
Mrs. Shirley David (on behalf of Mrs. Bharathy Jacob)	M.Sc. (Nursing), RN, RM	Dean, College of Nursing, CMC.	
Rev. Dr. T. Arul Dhas	M.Sc., BD, Ph.D.	Chaplain, CMC	
Dr. Jayaprakash Muliyil	BSC, MBBS, MD, MP DrPH(Epid), DMHC	Academic Officer, CMC	
Dr. P. Zachariah	MBBS, MD	Retired Professor	Non-CMC Staff
Mr. Harikrishnan	BL.	Lawyer	Non-CMC Staff.
Mr. Samuel Abraham	MA, PGDBA, PGDPM, M.Phil, BL.	Legal Advisor, CMC.	
Dr. Sujith Chandy	MBBS, MD	Professor, Pharmacology Dept. CMC.	
Dr. Denny Fleming	MBBS, MD	Professor, Pharmacology Dept. CMC.	
Mrs. S. Pattabiraman	BSc, DSSA	Social Worker, Vellore	Non-CMC-Staff
Dr. Suresh Devasahayam	BE, MS, PhD	Professor of Bioengineering, CMC	
Dr. Gagandeep Kang	MD, PhD, FRCPath.	Dy. Chairperson (IRB), Professor of Microbiology & Addl. Vice Principal (Research), CMC.	

We approve the project to be conducted in its presented form.

The Institutional Ethics Committee / Independent Ethics Committee expects to be informed about the progress of the project, any SAE occurring in the course of the project, any changes in the protocol and patient information/informed consent and asks to be provided a copy of the final report.

A sum of Rs. 35, 400/- (Rupees Thirty five thousand four hundred only) is sanctioned for 1 year out of which a maximum of Rs. 1,500/- can be spent for stationery, printing, Xeroxing and computer charges (if computers used are within the institution).

Yours sincerely,

L. Jeyaseelan.

Dr. L. Jeyaseelan, PhD
Secretary, IRB

Secretary
Institutional Review Board
(Ethics Committee)
Christian Medical College
Vellore - 632 002, Tamil Nadu, India

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APPENDIX 2

INDIVIDUAL CROSS-TABULATION ANALYSIS TABLES

SECTION 1. CROSS-TABULATION ANALYSIS BY FACTORS CONTRIBUTING TO A PATIENT BEING ADVISED TO SCREEN CONTACTS

Table 1. Sex of the patient by advise to undertake contact screening (N=84)

	ADVISED	NOT ADVISED	ODDS RATIO (95% CI)	SIGNIFICANCE (p VALUE)
MALE	19(31.1%)	42(68.9%)	1.023(0.497-2.106)	0.950
FEMALE	7(30.4%)	16(69.6%)		

Table 2. Age of the patient by advise to undertake contact screening (N=84)

	ADVISED	NOT ADVISED	ODDS RATIO (95% CI)	SIGNIFICANCE (p VALUE)
18-45 YEARS	11(29.7%)	26(70.3%)	0.932(0.487-1.781)	0.830
>45 YEARS	15(31.9%)	32(68.1%)		

Table 3. Education of the patient by advise to undertake contact screening (N=84)

	ADVISED	NOT ADVISED	ODDS RATIO (95% CI)	SIGNIFICANCE (p VALUE)
EDUCATED	18(26.1%)	51(73.9%)	0.489(0.264-0.907)	0.039
UNEDUCATED	8(53.3%)	7(46.7%)		

Table 4. Employment status of the patient by advise to undertake contact screening (N=84)

	ADVISED	NOT ADVISED	ODDS RATIO (95% CI)	SIGNIFICANCE (p VALUE)
EMPLOYED	15(30.6%)	34(69.4%)	0.974(0.511-1.858)	0.936
UNEMPLOYED	11(31.4%)	24(68.6%)		

Table 5. Marital status of the patient by advise to undertake contact screening (N=84)

	ADVISED	NOT ADVISED	ODDS RATIO (95% CI)	SIGNIFICANCE (p VALUE)
MARRIED	18(31.6%)	39(68.4%)	1.066(0.532-2.137)	0.857
OTHERS	8(29.6%)	19(70.4%)		

Table 6. Distance to PHI by advise to undertake contact screening (N=84)

	ADVISED	NOT ADVISED	ODDS RATIO (95% CI)	SIGNIFICANCE (p VALUE)
≤ 5Km	13(23.6%)	42(76.4%)	0.527(0.283-0.984)	0.046
>5 Km	13(44.8%)	16(55.2%)		

Table 7. Presence of any symptomatic or child contact by advise to undertake contact screening (N=84)

	ADVISED	NOT ADVISED	ODDS RATIO (95% CI)	SIGNIFICANCE (p VALUE)
SYMPTOMATIC CONTACTS PRESENT	12(60.0%)	8(40.0%)	2.743(1.528-4.924)	0.001
SYMPTOMATIC CONTACTS NOT PRESENT	14(21.9%)	50(78.1%)		

Table 8. Presence of any child contact by advise to undertake contact screening (N=84)

	ADVISED	NOT ADVISED	ODDS RATIO (95% CI)	SIGNIFICANCE (p VALUE)
CHILD CONTACT PRESENT	11(57.9%)	8(42.1%)	2.509(1.395-4.510)	0.004
NO CHILD CONTACT	15(23.1%)	50(76.9%)		

Table 9. Family history of tuberculosis by advise to undertake contact screening (N=84)

	ADVISED	NOT ADVISED	ODDS RATIO (95% CI)	SIGNIFICANCE (p VALUE)
FAMILY HISTORY PRESENT	8(29.6%)	19(70.4%)	0.938(0.468-1.881)	0.857
NO FAMILY HISTORY	18(31.6%)	39(68.4%)		

Table 10. Any Category II/ IV by advise to undertake contact screening (N=84)

	ADVISED	NOT ADVISED	ODDS RATIO (95% CI)	SIGNIFICANCE (p VALUE)
ANY CAT II/ CAT IV	12(40.0%)	18(60.0%)	1.543(0.823-2.893)	0.181
CAT I	14(25.9%)	40(74.1%)		

Table 11. Any ever treated Relapse/Default/Failure by advise to undertake contact screening (N=84)

	ADVISED	NOT ADVISED	ODDS RATIO (95% CI)	SIGNIFICANCE (p VALUE)
ANY EVER TREATED RELAPSE/ DEFAULT/ FAILURE	8(38.1%)	13(61.9%)	1.333(0.682-2.607)	0.414
OTHERS	18(28.6%)	45(71.4%)		

Table 12. Any Default by advise to undertake contact screening (N=84)

	ADVISED	NOT ADVISED	ODDS RATIO (95% CI)	SIGNIFICANCE (p VALUE)
ANY DEFAULT	7(33.3)	14(66.7%)	1.105(0.542-2.253)	0.785
OTHERS	19(30.2%)	44(69.8%)		

SECTION 2. CROSS-TABULATION ANALYSIS BY FACTORS INFLUENCING PATIENTS TO UNDERTAKE CONTACT SCREENING

Table 13. Sex by contact screening (N=84)

	SCREENING DONE	SCREENING NOT DONE	ODDS RATIO (95% CI)	SIGNIFICANCE (p VALUE)
MALE	15(24.5%)	46(75.4%)		
FEMALE	4(17.4%)	19(82.6%)	1.414(0.524-3.817)	0.482

Table 14. Age of the patient by contact screening (N=84)

	SCREENING DONE	SCREENING NOT DONE	ODDS RATIO (95% CI)	SIGNIFICANCE (p VALUE)
18-45 YEARS	8(21.6%)	29(78.4%)		
>45 YEARS	11(23.4%)	36(76.6%)	0.924(0.414-2.061)	0.846

Table 15. Education of the patient by contact screening (N=84)

	SCREENING DONE	SCREENING NOT DONE	ODDS RATIO (95% CI)	SIGNIFICANCE (p VALUE)
EDUCATED	16(23.2%)	53(76.8%)		
UNEDUCATED	3(20.0%)	12(80.0%)	1.159(0.386-3.481)	0.789

Table 16. Employment status of the patient by contact screening (N=84)

	SCREENING DONE	SCREENING NOT DONE	ODDS RATIO (95% CI)	SIGNIFICANCE (p VALUE)
EMPLOYED	8(16.3%)	41(83.7%)		
UNEMPLOYED	11(31.4%)	24(68.6%)	0.519(0.233-1.157)	0.103

Table 17. Marital status of the patient by contact screening (N=84)

	SCREENING DONE	SCREENING NOT DONE	ODDS RATIO (95% CI)	SIGNIFICANCE (p VALUE)
MARRIED	15(26.3%)	42(73.7%)		
OTHERS	4(14.8%)	23(85.2%)	1.776(0.651-4.845)	0.239

Table 18. Distance to PHI by contact screening (N=84)

	SCREENING DONE	SCREENING NOT DONE	ODDS RATIO (95% CI)	SIGNIFICANCE (p VALUE)
≤ 5Km	14(25.5%)	41(74.5%)		
>5 Km	5(17.2%)	24(82.8%)	1.476(0.590-3.692)	0.392

Table 19. Presence of any symptomatic or child contact by contact screening (N=84)

	SCREENING DONE	SCREENING NOT DONE	ODDS RATIO (95% CI)	SIGNIFICANCE (p VALUE)
SYMPTOMATIC CONTACTS PRESENT	13(65.0%)	7(35.0%)		
SYMPTOMATIC CONTACTS NOT PRESENT	6(9.4%)	58(90.6%)	6.933(3.033-15.850)	<0.001

Table 20. Presence of any child contact by contact screening (N=84)

	SCREENING DONE	SCREENING NOT DONE	ODDS RATIO (95% CI)	SIGNIFICANCE (p VALUE)
CHILD CONTACT PRESENT	12(63.2%)	7(36.8%)	5.865(2.690-12.787)	<0.001
NO CHILD CONTACT	7(10.8%)	58(89.2%)		

Table 21. Family history of tuberculosis by contact screening (N=84)

	SCREENING DONE	SCREENING NOT DONE	ODDS RATIO (95% CI)	SIGNIFICANCE (p VALUE)
FAMILY HISTORY PRESENT	8(29.6%)	19(70.4%)	1.535(0.699-3.374)	0.291
NO FAMILY HISTORY	11(19.3%)	46(80.7%)		

Table 22. Any Category II/ IV by contact screening (N=84)

	SCREENING DONE	SCREENING NOT DONE	ODDS RATIO (95% CI)	SIGNIFICANCE (p VALUE)
ANY CAT II/ CAT IV	11(36.7%)	19(63.3%)	2.475(1.119-5.475)	0.022
CAT I	8(14.8%)	46(85.2%)		

Table 23. Any ever treated Relapse/Default/Failure by contact screening (N=84)

	SCREENING DONE	SCREENING NOT DONE	ODDS RATIO (95% CI)	SIGNIFICANCE (p VALUE)
ANY EVER TREATED RELAPSE/ DEFAULT/ FAILURE	9(42.9%)	12(57.1%)	2.700(1.272-5.733)	0.010
OTHERS	10(15.9%)	53(84.1%)		

Table 24. Any Default by contact screening (N=84)

	SCREENING DONE	SCREENING NOT DONE	ODDS RATIO (95% CI)	SIGNIFICANCE (p VALUE)
ANY DEFAULT	4(19.0%)	17(81.0%)	0.800(0.298-2.145)	0.651
OTHERS	15(23.8%)	48(76.2%)		

SECTION 3. CROSS-TABULATION ANALYSIS BY FACTORS POTENTIALLY INFLUENCING PATIENTS' AWARENESS THAT CONTACTS NEED TO BE SCREENED

Table 25. Sex by awareness that contacts need to be screened (N=84)

	AWARE	NOT AWARE	ODDS RATIO (95% CI)	SIGNIFICANCE (p VALUE)
MALE	49(80.3%)	12(19.7%)		
FEMALE	16(69.6%)	7(30.4%)	1.155(0.858-1.555)	0.239

Table 26. Age by awareness that contacts need to be screened (N=84)

	AWARE	NOT AWARE	ODDS RATIO (95% CI)	SIGNIFICANCE (p VALUE)
18-45 YEARS	33(89.2%)	4(10.8%)		
>45 YEARS	32(68.1%)	15(31.9%)	1.310(1.045-1.641)	0.022

Table 27. Education by awareness that contacts need to be screen (N=84)

	AWARE	NOT AWARE	ODDS RATIO (95% CI)	SIGNIFICANCE (p VALUE)
EDUCATED	59(85.5%)	10(14.5%)		
UNEDUCATED	6(40.0%)	9(60.0%)	2.138(1.142-4.003)	<0.001

Table 28. Employment status by awareness that contacts need to be screened (N=84)

	AWARE	NOT AWARE	ODDS RATIO (95% CI)	SIGNIFICANCE (p VALUE)
EMPLOYED	43(87.8%)	6(12.2%)		
UNEMPLOYED	22(62.9%)	13(37.1%)	1.396(1.060-1.839)	0.007

Table 29. Marital status by awareness that contacts need to be screened (N=84)

	AWARE	NOT AWARE	ODDS RATIO (95% CI)	SIGNIFICANCE (p VALUE)
MARRIED	44(77.2%)	13(22.8%)		
OTHERS	21(77.8%)	6(22.2%)	0.992(0.776-1.269)	0.952

Table 30. Distance to PHI by awareness that contacts need to be screened (N=84)

	AWARE	NOT AWARE	ODDS RATIO (95% CI)	SIGNIFICANCE (p VALUE)
≤ 5Km	42(76.4%)	13(23.6%)	0.963(0.760-1.220)	0.759
>5 Km	23(79.3%)	6(20.7%)		

Table 31. Presence of symptomatic or child contacts by awareness that contacts need to be screened (N=84)

	AWARE	NOT AWARE	ODDS RATIO (95% CI)	SIGNIFICANCE (p VALUE)
SYMPTOMATIC CONTACTS PRESENT	19(95.0%)	1(5.0%)	1.322(1.100-1.588)	0.031
SYMPTOMATIC CONTACTS NOT PRESENT	46(71.9%)	18(28.1%)		

Table 32. Presence of child contacts by awareness that contacts need to be screened (N=84)

	AWARE	NOT AWARE	ODDS RATIO (95% CI)	SIGNIFICANCE (p VALUE)
CHILD CONTACT PRESENT	18(94.7%)	1(5.3%)	1.310(1.090-1.575)	0.040
NO CHILD CONTACT	47(72.3%)	18(27.7%)		

Table 33. Family history of TB by awareness that contacts need to be screened (N=84)

	AWARE	NOT AWARE	ODDS RATIO (95% CI)	SIGNIFICANCE (p VALUE)
FAMILY HISTORY PRESENT	25(92.6%)	2(7.4%)	1.319(1.080-1.612)	0.022
NO FAMILY HISTORY	40(70.2%)	17(29.8%)		

Table 34. Any Category II/ Category IV by awareness that contacts need to be screened (N=84)

	AWARE	NOT AWARE	ODDS RATIO (95% CI)	SIGNIFICANCE (p VALUE)
ANY CAT II/ CAT IV	24(80.0%)	6(20.0%)	1.054(0.834-1.331)	0.669
CAT I	41(75.9%)	13(24.1%)		

Table 35. Any ever treated Relapse/Default/Failure by awareness that contacts need to be screened (N=84)

	AWARE	NOT AWARE	ODDS RATIO (95% CI)	SIGNIFICANCE (p VALUE)
ANY EVER TREATED RELAPSE/ FAILURE/ DEFAULT	17(81.0%)	4(19.0%)	1.063(0.828-1.363)	0.651
OTHERS	48(76.2%)	15(23.8%)		

Table 36. Any Default by awareness that contacts need to be screened (N=84)

	AWARE	NOT AWARE	ODDS RATIO (95% CI)	SIGNIFICANCE (p VALUE)
ANY DEFAULT	14(66.7%)	7(33.3%)	0.824(0.595-1.140)	0.175
OTHERS	51(81.0%)	12(19.0%)		

SECTION 4. CROSS-TABULATION ANALYSIS BY FACTORS POTENTIALLY INFLUENCING PATIENTS' AWARENESS REGARDING HOW TO SCREEN CONTACTS

Table 37. Sex by awareness on how contacts can be screened (N= 65)

	AWARE	NOT AWARE	ODDS RATIO (95% CI)	SIGNIFICANCE (p VALUE)
MALE	31(63.3%)	18(36.7%)	0.723(0.545-0.959)	0.068
FEMALE	14(87.5%)	2(12.5%)		

Table 38. Age by awareness on how contacts can be screened (N= 65)

	AWARE	NOT AWARE	ODDS RATIO (95% CI)	SIGNIFICANCE (p VALUE)
18-45 YEARS	24(72.7%)	9(27.3%)	1.108(0.800-1.536)	0.535
>45 YEARS	21(65.6%)	11(34.4%)		

Table 39. Education by awareness on how contacts can be screened (N= 65)

	AWARE	NOT AWARE	ODDS RATIO (95% CI)	SIGNIFICANCE (p VALUE)
EDUCATED	41(69.5%)	18(30.5%)	1.042(0.578-1.881)	0.886
UNEDUCATED	4(66.7%)	2(33.3%)		

Table 40. Employment status by awareness on how contacts can be screened (N= 65)

	AWARE	NOT AWARE	ODDS RATIO (95% CI)	SIGNIFICANCE (p VALUE)
EMPLOYED	30(69.8%)	13(30.2%)	1.023(0.723-1.447)	0.896
UNEMPLOYED	15(68.2%)	7(31.8%)		

Table 41. Marital status by awareness on how contacts can be screened (N= 65)

	AWARE	NOT AWARE	ODDS RATIO (95% CI)	SIGNIFICANCE (p VALUE)
MARRIED	29(65.9%)	15(34.1%)	0.865(0.628-1.191)	0.401
OTHERS	16(76.2%)	5(23.8%)		

Table 42. Distance to PHI by awareness on how contacts can be screened (N= 65)

	AWARE	NOT AWARE	ODDS RATIO (95% CI)	SIGNIFICANCE (p VALUE)
≤ 5Km	31(73.8%)	11(26.2%)	1.213(0.834-1.762)	0.280
>5 Km	14(60.9%)	9(39.1%)		

Table 43. Presence of symptomatic or child contacts by awareness on how contacts can be screened (N= 65)

	AWARE	NOT AWARE	ODDS RATIO (95% CI)	SIGNIFICANCE (p VALUE)
SYMPTOMATIC CONTACTS PRESENT	13(68.4%)	6(31.6%)	0.984(0.686-1.410)	0.928
SYMPTOMATIC CONTACTS NOT PRESENT	32(69.6%)	14(30.4%)		

Table 44. Presence of child contacts by awareness on how contacts can be screened (N= 65)

	AWARE	NOT AWARE	ODDS RATIO (95% CI)	SIGNIFICANCE (p VALUE)
CHILD CONTACT PRESENT	12(66.7%)	6(33.3%)	0.949(0.652-1.383)	0.782
NO CHILD CONTACT	33(70.2%)	14(29.8%)		

Table 45. Family history of TB by awareness on how contacts can be screened (N= 65)

	AWARE	NOT AWARE	ODDS RATIO (95% CI)	SIGNIFICANCE (p VALUE)
FAMILY HISTORY PRESENT	19(76.0%)	6(24.0%)	1.169(0.852-1.605)	0.350
NO FAMILY HISTORY	26(65.0%)	14(35.0%)		

Table 46. Any Category II/ Category IV by awareness on how contacts can be screened (N= 65)

	AWARE	NOT AWARE	ODDS RATIO (95% CI)	SIGNIFICANCE (p VALUE)
ANY CAT II/ CAT IV	17(70.8%)	7(29.2%)	1.037(0.745-1.444)	0.830
CAT I	28(68.3%)	13(31.7%)		

Table 47. Any ever treated Relapse/Default/Failure by awareness on how contacts can be screened (N= 65)

	AWARE	NOT AWARE	ODDS RATIO (95% CI)	SIGNIFICANCE (p VALUE)
ANY EVER TREATED RELAPSE/ DEFAULT/ FAILURE	12(70.6%)	5(29.4%)	1.027(0.715-1.474)	0.888
OTHERS	33(68.8%)	15(31.3%)		

Table 48. Any Default by awareness on how contacts can be screened (N= 65)

	AWARE	NOT AWARE	ODDS RATIO (95% CI)	SIGNIFICANCE (p VALUE)
ANY DEFAULT	8(57.1%)	6(42.9%)	0.788(0.485-1.278)	0.269
OTHERS	37(72.5%)	14(27.5%)		

APPENDIX 3.

INFORMATION SHEET (ENGLISH)

INFORMATION SHEET

Name of the study: A study on the Household Contacts Of Sputum Positive Pulmonary Tuberculosis in a rural area in South India.

You are invited to participate in the above mentioned study. This is a research project which aims to find out details about the screening of household contacts of sputum positive pulmonary tuberculosis patients in the rural population in Kaniyambadi Tuberculosis Unit area.

The investigator will come and perform the following procedures:
Ask you a few questions
Give health education regarding the importance of screening of household contacts of sputum positive pulmonary Tuberculosis patients.
Based on your responses, the investigator may advise the following free tests for a household contact: i) Sputum examination
ii) An injection in the left forearm
iii) Chest X-Ray

There are no major risks associated with these procedures. The injection in the left forearm may be painful.

By participating in this study (if warranted) your household contact(s) get a free chest X-Ray, sputum examination and Mantoux test, which would help detect Tuberculosis. The results will help the investigators give the household contact(s) treatment if the household contact(s) have Tuberculosis. If any serious illness is detected, then your household contact(s) will be appropriately referred to CHAD Hospital, Bagayam, CMC Hospital, Vellore, or Tuberculosis Research Centre, Tambaram, Chennai.

The information obtained from you may be used for publication in scientific journals. All information collected from you will be kept confidential. No personal details will be revealed to anyone. Participation in this study is entirely voluntary. You may withdraw from the study or refuse to participate at any point of time.

APPENDIX 4

CONSENT FORM (ENGLISH)

INFORMED CONSENT

Study Title: A study on the Household contacts of Sputum Positive Tuberculosis patients

in a rural area in South India.

Subject's Initials: _____ Subject's Name: _____
Date of Birth / Age:_____
Please initial box
(Subject)

(i) I confirm that I have read and understood the information sheet dated _____ for the above study and have had the opportunity to ask questions. [ ]

(ii) I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. [ ]

(iii) I understand that the Sponsor of the clinical trial, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my child/ward/ spouse/ other household contacts' health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my child/ward/ spouse/ other household contacts' identity will not be revealed in any information released to third parties or published. [ ]

(iv) I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s) [ ]

(v) I agree to take part in the above study. [ ]

Signature (or Thumb impression) of the Patient/Parent/Spouse/Legally Acceptable Representative:_____
Date: _____/_____/_____
Signatory's Name: _____

Signature of the Investigator: _____
Date: _____/_____/_____
Study Investigator's Name: _____

Signature of the Witness: _____
Date:_____/_____/_____
Name of the Witness: _____

APPENDIX 5

INFORMATION SHEET (TAMIL)

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MuhŒ¢Áæ‹ jiy¥ò

bj‹ ïªÂahé‹ »uhk¤Âš cŸs Eiupuš fhr nehahëfë‹ Å£oš bjhl®òŸs eg®fël« el¤j¥gL« MŒÎ.

nk‰T¿a MuhŒ¢Áæš g§nf‰f Ú§fŸ miH¡fg»Ö®fŸ. Eiupuš fhr nehahëfSl‹ bjhl®ò cŸst®fS¡F brŒj gçnrhjidfŸ g‰¿ bjçªJ bfhŸtJ ïªj MuhŒ¢Áæ‹ neh¡f«.

MuhŒ¢Á¡fhf bjçªJbfhŸs¥g£l gFÂ fhrnehŒ Á»¢ir braš gL¤J« fâa«ghot£lhu«.

MuhŒ¢Áahs® Å£o‰F tªJ Ñœf©l Kiwfis filÃo¥gh®.

c§fël« Áy nfŸéfŸ nf£gh®.

rëæš fhrnehŒ »Uä cŸst®fël« bjhl®ò cŸst®fS¡F gçnrhjid brŒa nt©oaÂ‹ mtÁa¤ij¥ g‰¿ Rfhjhu fšé më¥gh®.

mjid mo¥gilahf bfh©L MuhŒ¢Áahs® Ñœf©l gçnrhjidfŸ brŒtj‰F m¿Îiw TWth®.

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ÏlJ ifæš CÁ

kh®ò v¡°nu

ïªj gçnrhjidædhš vªjéjkhd ghÂ¥ò« Ïšiy. ifæš nghL« CÁ xU ntis tè¡fyh«.

ïªj MuhŒ¢Áæš g§bfL¥gÂ‹ _ykhf njit ÏUªjhš Ïytrkhf kh®ò v¡°nu , rë gçnrhjid fhr nehŒ ÏU¡»wjh v‹gij f©l¿Í« nrhjid CÁ nghl¥gL«. mj‹ _ykhf fhr nehŒ f©l¿a¥g£lhš mt®fS¡F itÂa« brŒa MuhŒ¢Áahs®fS¡F cjÎ«. VjhtJ ga¥gL¥ goahd éahÂ f©l¿a¥g£lhš bjhl®ò cŸst®fŸ rh£ kU¤Jtkid ghfha«, »¿¤Jt kU¤Jtkid ntÿ® mšyJ fhr nehŒ MuhŒ¢Á ika« jh«gu« br‹id¡F bršYkhW gçªJiu brŒa¥gLth®fŸ.

c§fël« ÏUªJ bgw¥gL« jftšfŸ éŠrhd ò¤jf¤Âš btëæl¥glyh«. c§fël« ÏUªJ bgw¥gL« jftšfŸ g¤Âukhf e«Ã¡ifahf ghJfh¡f¥gL«. jå¥g£l jftšfŸ ahçlK« Twkh£nlh«. ïªj MuhŒ¢Áæš Ú§fŸ jhdhf K‹tªJ g§nf‰fyh«. ïªj MuhŒ¢ÁæYUªJ Ú§fŸ c§fŸ éU¥g¥go éy» bfhŸsyh« mšyJ v¥nghJ nt©LkhdhY« ãW¤Â¡ bfhŸsyh«.

APPENDIX 6

CONSENT FORM (TAMIL)

x¥òjš got«

bj‹ ïªÂahé‹ »uhk¤Âš cŸs Eiupuš fhr nehahëfë‹ Å£oš bjhl®òŸs eg®fël« el¤j¥gL« MŒÎ.

MuhŒ¢Áæš g§bfL¥gtç‹ KjbyG¤J:_____

MuhŒ¢Áæš g§bfL¥gtç‹ bga® : _____

Ãwªj njÂ / taJ : ____/_____/_____ _____

1 Ïªj MuhŒ¢Áia g‰¿ eh‹ go¤J, òçªJ bfh©nl‹ v‹gij cWÂ brŒ»nw‹. nkY« nfŸéfŸ nf£gj‰F vd¡F thŒ¥gë¡f¥g£lJ.

2 v‹ FHªij / kidé / fzt® / k‰wf®fŸ Ïªj MuhŒ¢Áæš Rakhf g§bfL¡fyh« vd bjçªJbfh©nl‹. v¥nghJ nt©khdhY« v‹Dila kU¤Jt njitfŸ k‰W« r£l ççikfŸ ghÂ¡fht©z«, fhuz§fŸ vJÎ« Twhkš Ïªj MuhŒ¢Áæš ÏUªJ éy»bfhŸs vd¡F ççik cŸsJ v‹gij bjçªJŸns‹.

3 Ïªj MuhŒ¢Áæ‹ bghW¥ghs®, cl‹ ntiy brŒgt®, XG¡féa‰ bra‰FG k‰W« f£Lgh£L thça« M»nah®, el¤Â¡ bfh©oU¡F« MuhŒ¢Á nkY« el¡f ÏU¡F« MuhŒ¢Áæš ÏUªJ eh‹ éy»dhY« v‹ FHªij / kidé / fzt® / v‹Dl‹ tÁ¡F« cwéd®fë‹ gÂntLfis gh®¡f v‹Dila mDkÂ njitæšiy v‹gij e‹F m¿ªÂU¡»nw‹. nkY« v‹ FHªij / kidé / fzt® / v‹Dl‹ tÁ¡F« cwéd®fis g‰¿a jftš mšyJ milahs¤ij és«gugL¤Jnth mšyJ _‹whtJ egU¡F bjça¥gL¤j kh£lh® v‹gij m¿ªÂU¡»nw‹.

4 Ïªj MuhŒ¢Áæš ÏUªJ bgw¥gL« jftšfS« , gçnrhjid KoÎfS« éŠrhd rh®ªj fhça¤Â‰F ga‹gL¤jyh« v‹W mDkÂ më¡»nw‹,

5 Ïªj MuhŒ¢Áæš v‹ FHªij / kidé / fzt® k‰W« FL«g m§f¤Âd® g§nf‰gÂš vd¡F r«kj«.

6 eh‹ nk‰f©l MuhŒ¢Áæš g§nf‰f r«kÂ¡»nw‹.

nehahë / bg‰nwh® / fzt® / kidé / r£l¥go ãaä¡f¥g£l

ÃuÂãÂæ‹ ifbah¥g« / bgUéuš ifnuif :

njÂ :

ifbaG¤J ÏLgtç‹ bga® : _____ njÂ:_____

MuhŒ¢Áahsç‹ ifbah¥g« : _____ njÂ:_____

MuhŒ¢Áahsç‹ bga® : _____ njÂ:_____

rh£Áahsç‹ ifbah¥g« : _____ njÂ:_____

rh£Áahsç‹ bga® : _____ njÂ:_____

APPENDIX 7.

STUDY QUESTIONNAIRE

STUDY ON THE HOUSEHOLD CONTACTS OF SPUTUM POSITIVE TUBERCULOSIS PATIENTS

1. DATE OF INTERVIEW ☐☐☐☐☐☐☐☐ 2. SERIAL NO. ☐☐☐ 3. ID NO. ☐☐☐☐☐☐☐☐☐

4. VILLAGE NAME ……..

5. NAME OF RESPONDENT …… 6. AGE ☐☐☐ 7. EDUCATION ☐☐☐☐ 8. OCCUPATION…….

9. PLACE OF WORK …… 10. MARITAL STATUS i) SINGLE ii) MARRIED iii) WIDOW/WIDOWER Iv) DIVORCED/SEPARATED ☐☐

11. SMOKER i)YES ii)NO iii)EX-SMOKER iv)PASSIVE SMOKER ☐☐ ALCOHOL CONSUMPTION i)YES ii)NO

FOR i) AND iii)→ a. BEEDI/ CIGARETTE b. PACK YEARS ☐☐ FOR iv) NO. OF YEARS ☐☐ DURATION

12. CONSUMES TOBACCO i)YES ii) NO ☐☐ 13. FAMILY HISTORY OF TUBERCULOSIS i) YES ii) NO ☐☐

SECTION 1 (PATIENT)

A. DETAILS OF ILLNESS

1. SYMPTOMS PRIOR TO DIAGNOSIS ☐☐

i) COUGH ≥ 2 WEEKS ii)FEVER ≥ 2 WEEKS iii)HEMOPTYSIS iv)DYSPNEA ≥ 2 WEEKS V)LOSS OF WEIGHT Vi) OTHERS (SPECIFY)

2. DURATION OF SYMPTOMS …… 3. DATE OF DIAGNOSIS ☐☐ ☐☐ ☐☐☐☐

4. DATE OF STARTING TREATMENT ☐☐ ☐☐ ☐☐☐☐ 5. DATE OF TREATMENT COMPLETION ☐☐ ☐☐ ☐☐☐☐

6. TREATMENT OBTAINED FROM (DOTS CENTER'S NAME) ……. 7. DURATION OF TREATMENT (IN MONTHS) ☐☐

8. TREATMENT CARD i)AVAILABLE ii) LOST iii) NOT GIVEN ☐☐☐ 10. ADVISED CONTACT SCREENING? I)YES ii)NO iii)YES,BUT LATER

9. ANY SYMPTOMATIC HOUSEHOLD CONTACTS DURING ILLNESS? i) YES ii) NO ☐☐ 11. CONTACT SCREENING DONE? I)YES ii)NO

IF YES, WHETHER SCREENED i) YES ii) NO ☐☐ METHOD OF SCREENING……

12. ANY CHILD CONTACTS? I)YES ii) NO 13. BCG SCAR PRESENT? I)YES ii)NO

14. TOTAL NUMBER OF CHILD CONTACTS…….. 15. INH PROPHYLAXIS GIVEN? I)YES ii)NO 16. IF YES, DURATION……

B. AWARENESS REGARDING SCREENING OF HOUSEHOLD CONTACTS

1. DO HOUSEHOLD CONTACTS NEED TO BE SCREENED?

i) YES ☐

a. WHY? ……

b. HOW CAN THEY BE SCREENED? ……..

ii) NO ☐

SECTION II (HOUSEHOLD CONTACTS)

S. NO.	NAME	AGE	SEX	EDU. QUAL.	MARITAL STATUS	REL. TO PATIENT	DURATION OF CONTACT	SCREENED FOR TB?			CURRENTLY SYMPTOMATIC?		
								NO	YES		NO	YES	
									HOW?	RESULT		SYMPTOMS	DURATION